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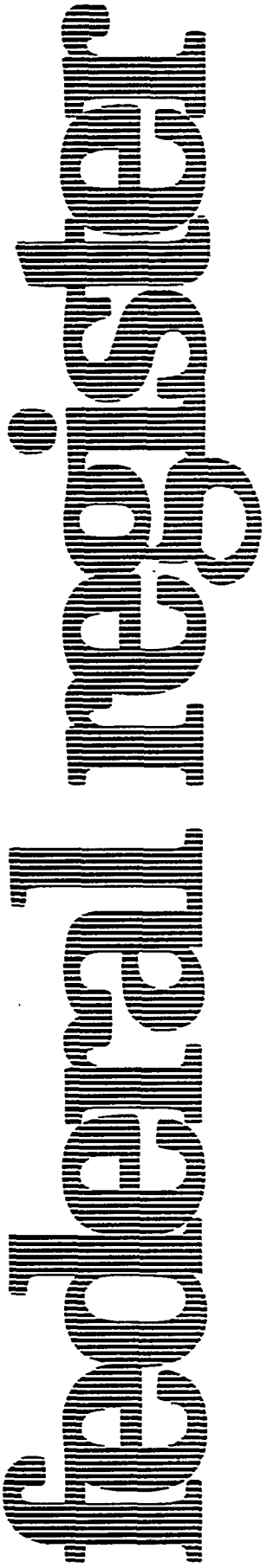

Tuesday
May 27, 1980

Highlights

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FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

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Highlights

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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 213

Excepted Service: Department of Health, Education, and Welfare

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: Positions on an emergency staff in the Office of the Secretary (HEW) to assist in the resettlement of the current wave of Cuban refugees are excepted under Schedule A because it is impracticable to hold an examination for them.

EFFECTIVE DATE: May 21, 1980.

FOR FURTHER INFORMATION CONTACT:
On position authority: William Bohling, Office of Personnel Management, 202–632–6000. On position content: William Hanks, Department of Health, Education, and Welfare, 202–472–3776.

Office of Personnel Management.
Beverly M. Jones,
Issuance System Manager.

Accordingly, 5 CFR 213.3116(k) is added as set out below:

§ 213.3116 Department of Health, Education, and Welfare.

* * * * *

(k) Office of the Secretary

(1) Not to exceed 500 staff positions, GS–15 and below, for an emergency staff to assist in the resettlement of the current wave of Cuban refugees. Employment under this authority may not exceed September 30, 1982.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp. p. 218)

[FR Doc. 80-16186 Filed 5-23-80; 10:06 am]
BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products; Prohibitions and Restrictions

Correction

In FR Doc. 80–14492, published at page 31572, on Tuesday, May 13, 1980 make the following corrections:

1. On page 31572:

a. Under SUMMARY, in the first column, in the fifth line, "classes of nursery stocks, and certain" should be corrected to read "classes of nursery stock, and certain";

b. In the second column, in the last paragraph, "(a) Is is imported into the United" should be corrected to read "(a) It is imported into the United";

c. In the third column, in the last paragraph, in the fifth line "Ploynesia" should be corrected to read "Polynesia";

2. On page 31573:

a. In the first column, in the first full paragraph, in the eleventh line "that" should be corrected to read "at";

b. In the first column, in the last paragraph, in the fourteenth line "distructive" should be corrected to read "destructive";

3. On page 31577, in the third column, in the first complete paragraph, in the thirteenth line "cutting" should be corrected to read "cuttings";

4. On page 31578, in the third column, in the thirteenth line ". . . final fule" should be corrected to read ". . . final rule";

5. On page 31581, in the first column, in the first complete paragraph, in the ninth line "*Ligustrium*" should be corrected to read "*Ligustrum*";

6. On page 31583, in the third colum, first complete paragraph in the sixth line, "PBQ" should be corrected to read "PPQ";

7. On page 31584, in the second column, in the first complete paragraph, in the third line "i.e., and inspection . . ." should be corrected to read "i.e., an inspection . . .";

8. On page 31585, in the third column, in the twelfth line "imporatation" should be corrected to read "importation";

9. In § 319.37–2(a), in the table on page 31587, the Prohibited Article "*Andonidia* spp" should be corrected to read "*Adonidia* spp";

10. In § 319.37–2(a), in the table on page 31588, in the Prohibited Article "*Morus* spp (mulberry)", in the third column "Mulberry mosiac virus" should be corrected to read "Mulberry mosaic virus";

11. On page 31591, in the third column:

a. In paragraph (d), in the first line "articles" should be corrected to read "article";

b. In paragraph (e), in the eleventh line "accurtate" should be corrected to read "accurate";

12. On page 31592, in § 319.37–6(c), in the list in the second column, the third entry "*Annoa*" should be corrected to read "*Annona*";

13. In § 319.37–7(a), in the table on page 31593:

a. In the first column, under the Restricted Article "*Bromeliaceae* (bromeliads)" "distined" should be corrected to read "destined";

b. In the second column, under the Restricted Article "*Mahoberberis* ssp", in the fifth line "(plants of all specise and" should be corrected to read "(plants of all species and";

c. In the second column, under the Restricted Article "Nut and fruit articles" the words "All except Canada" should be deleted.

BILLING CODE 1505-01-M

Agricultural Marketing Service

7 CFR Part 905

[Orange, Grapefruit, Tangerine, and Tangelo Regulation 3, Amdt. 11]

Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Grapefruit Grade and Size Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Amendment to final rule.

SUMMARY: This amendment lowers the minimum grade and size requirements for domestic and export shipments of seedless grapefruit for the period May 21–August 24, 1980. The grade requirements are lowered to U.S. No. 2 Russet, from Improved No. 2, for all such grapefruit, while the size requirement is lowered to 3⁵⁄₁₆ inches in diameter, from 3⁹⁄₁₆ inches, for domestic shipments of grapefruit other than pink. The minimum size requirement for domestic shipments

of pink seedless grapefruit, and export shipments of all seedless grapefruit is currently 3 5/16 inches. The change in minimum grade and size is necessary because of current and prospective supply and demand for the fruit and to maintain orderly marketing conditions in the interest of producers and consumers.

EFFECTIVE DATE: May 21, 1980.

FOR FURTHER INFORMATION CONTACT: Malvin E. McGaha 202–447–5975.

SUPPLEMENTARY INFORMATION: Findings. (1) This regulation is issued under the marketing agreement and Order No. 905, both as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines and tangelos grown in Florida. The agreement and order are effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This action is based upon the recommendation and information submitted by the Citrus Administrative Committee established under the order, and upon other available information. It is found that the regulation of grapefruit, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) This amendment reflects the Department's appraisal of the current and prospective supply and market demand conditions for grapefruit. It is designed to assure an ample supply of acceptable quality grapefruit to consumers consistent with the quality of the crop.

(3) It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this amendment is based and the effective date necessary to effectuate the declared policy of the act. Growers, handlers and other interested persons were given an opportunity to submit information and views on the amendment at an open meeting, and the amendment relieves restrictions on the handling of Florida grapefruit. It is necessary to effectuate the declared purposes of the act to make the regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

Further, in accordance with procedures in Executive Order 12044, the emergency nature of this regulation warrants publication without opportunity for further public comments. The regulation has not been classified significant under USDA criteria for implementing the Executive Order. An Impact Analysis is available from Malvin E. McGaha, Fruit Branch, Fruit and Vegetable Division, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

Accordingly, it is found that the provisions of § 905.303 (Orange Grapefruit, Tangerine, and Tangelo Regulation 3) (44 FR 59195; 65962; 66779; 69917; 72025; 74794; 45 FR 6591; 7999; 12773; 24440; and 27739), relating to grapefruit, are amended by revising Table I, paragraph (a) applicable to domestic shipments, and Table II, paragraph (b) applicable to export shipments, to read as follows:

§ 905.303 Orange, grapefruit, tangerine, and tangelo regulation 3.

(a) * * *

Table I

Variety	Regulation period	Minimum grade	Minimum diameter (inches)
(1)	(2)	(3)	(4)
Grapefruit: Seedless, except Pink..	May 21 through Aug. 24, 1980	U.S. No. 2 Russet	3 5/16
	Aug. 25 through Oct. 12, 1980	Improved No. 2	3 5/16
Grapefruit: Seedless, Pink	May 21 through Aug. 24, 1980	U.S. No. 2 Russet	3 5/16
	Aug. 25 through Oct. 12, 1980	Improved No. 2	3 5/16

(b) * * *

Table II

Variety	Regulation period	Minimum grade	Minimum diameter (inches)
(1)	(2)	(3)	(4)
Grapefruit: Seedless, except Pink..	May 21 through Aug. 24, 1980	U.S. No. 2 Russet	3 5/16
	Aug. 25 through Oct. 12, 1980	Improved No. 2	3 5/16
Grapefruit: Seedless, Pink	May 21 through Aug. 24, 1980	U.S. No. 2 Russet	3 5/16
	Aug 25 through Oct. 12, 1980	Improved No. 2	3 5/16

* * * * * * * *

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: May 21, 1980.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 80-16018 Filed 5-23-80; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 11 and 13

[Docket No. 20359; Amdt. Nos. 11-17 and 13-16]

Revised Mailing Addresses

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: These amendments specify the office to which certain petitions for rulemaking or exemption must be submitted and update the reference numbers of the Enforcement Docket. Consistent with Executive Order 12044, these amendments simplify the process by which petitions are submitted. In addition, these amendments reflect a redesignation of certain offices within FAA Headquarters.

DATES: Effective May 27, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. Edward P. Faberman, Regulations and Enforcement Division (AGC-200), Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 755–8716.

SUPPLEMENTARY INFORMATION: Part 11 of the Federal Aviation Regulations (FAR) states that any interested person

may petition the Administrator for rulemaking or exemption. A specific office is not designated where these petitions must be submitted. As a result of this, petitions are submitted to various offices within the agency. Therefore, certain petitions have been misdirected resulting in increased processing time. In order to maintain a current public docket of petitions received and to eliminate processing delays, this amendment requires that certain petitions for rulemaking or exemption be submitted to the Rules Docket (AGC-204), Federal Aviation Administration, 800 Independence Avenue, SW, Washington, D.C. 20591. The amendment also clarifies where certain other petitions must be submitted. This amendment does not change the procedures relating to (1) airspace assignment and use (which must pursuant to 14 CFR 11.63(a) be filed with the appropriate Regional Director); (2) Petitions for exemption under Part 139 (which must pursuant to 14 CFR 11.25(b)(2)(i) be filed with the appropriate FAA airport field office in whose area the petitioner proposes to establish or has established its airport); and, (3) Airworthiness Directives (which must pursuant to 14 CFR 11.83 be filed with the Director responsible for the product involved).

In connection with petitions filed under the provisions of § 11.25, among other things they must set forth the text or substance of the rule or amendment proposed, the interests of the petitioner in the action requested; in the case of a petition for exemption, the nature and extent of the relief sought, the reasons why it would be in the public interest, and if appropriate in the case of an exemption, the reason why the exemption would not adversely affect safety.

Certain portions of the Office of the Chief Counsel have been assigned different office routing symbols. As a result of this, it is necessary to delete the symbols currently contained in the regulations and to replace them with the newly assigned ones. FAR Part 13 lists two of these reference numbers in mailing addresses and, therefore, needs to be updated.

Since these amendments are editorial in nature and impose no additional burden on any person, notice and public procedure are unnecessary and good cause exists for making them effective in less than 30 days.

The Amendments

Accordingly, Parts 11 and 13 of the Federal Aviation Regulations (14 CFR Parts 11 and 13) are amended, effective May 27, 1980, as follows:

PART 11—GENERAL RULE-MAKING PROCEDURES

1. By amending § 11.25 by revising paragraph (b)(2)(ii) and adding new subdivisions (iii) and (iv) to read as follows:

§ 11.25 Petitions for rulemaking or exemptions.

* * * * *

(b) * * *

(2) * * *

(ii) To the Director having Airworthiness Directive responsibility for the product involved in the case of petitions filed in accordance with Subpart D of this Part.

(iii) To the Federal Air Surgeon (AAM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591, in the case of a petition for exemption filed under Part 67 of this chapter; and

(iv) To the Rules Docket (AGC-204), Federal Aviation Administration, 800 Independence Avenue, Washington, D.C. 20591, in all other cases.

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

§ 13.5 [Amended]

2. By amending § 13.5, paragraphs (b)(2) and (k) by deleting the words (AGC-27) and substituting for them the words (AGC-209).

(Secs. 313(a), 314(a), 601 through 610, and 1102 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 through 1430, 1502; sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Note.—The Federal Aviation Administration has determined that this document involves a regulation that is not significant under Executive Order 12044, as implemented by the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). In addition, since these documents are editorial in nature and impose no additional burden on any person, the Federal Aviation Administration has determined that there will be no economic impact and thus no evaluation is required.

Issued in Washington, D.C., on May 16, 1980.

Langhorne Bond,

Administrator.

[FR Doc. 80-15606 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 80-CE-17-AD; Amdt. 39-3768]

Airworthiness Directive; Cessna Models 500, 501, 550, and 551 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correction of final rule.

SUMMARY: This action corrects a rule issued on April 24, 1980, and appearing in FR Doc. 80-13469 on pages 29560 and 29561 in the issue of Monday, May 5, 1980 (80-CE-17-AD). A Model 500 airplane serial number was incorrectly cited in the applicability statement of the Airworthiness Directive (AD) which necessitates this correction.

EFFECTIVE DATE: May 16, 1980.

FOR FURTHER INFORMATION CONTACT: Robert L. Klapprott, Aerospace Engineer, Wichita Engineering and Manufacturing District Office, FAA, Room 238, Terminal Building No. 2299, Mid-Continent Airport, Wichita, Kansas; telephone (316) 942-4281.

SUPPLEMENTARY INFORMATION: The FAA issued a Final Rule AD with an effective date of May 12, 1980. In the applicability statement of the AD, Cessna Model 500 airplane Serial Number 500-0370 was erroneously cited as Serial Number 500-0376. Action is taken herein to make this correction. Since the change is editorial in nature, notice and public procedure thereon are not considered necessary.

In FR Doc. 80-13469 appearing on page 29561 in the Federal Register of May 5, 1980, make the following correction: (1) In the applicability statement under Model 500, Serial No. "500-0376" should be corrected to read "500-0370."

(Sec. 313(a), 601 and 603 of the Federal Aviation Act of 1958, as amended, (49 U.S.C. 1354(a), 1421 and 1423; sec. 6(c) Department of Transportation Act (49 U.S.C. 1655(c)); sec. 11.89 of the Federal Aviation Regulations (14 CFR 11.89))

Issued in Kansas City, Missouri, on May 16, 1980.

Paul J. Baker,

Director, Central Region.

[FR Doc. 80-15830 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 80-EA-14, Amdt. 39-3778]

Airworthiness Directives; Boeing Vertol Model 107-II

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment issues a new airworthiness directive, applicable to Boeing Vertol 107–II type rotorcraft, which requires a removal of the forward spring of the cyclic stick boots, P/N 107S2226–9, –13, –17. This results from the determination that the spring was restricting cyclic stick travel.

EFFECTIVE DATE: May 28, 1980. Compliance is required as set forth in the AD.

ADDRESSES: Boeing Vertol Service Bulletins may be acquired from the manufacturer at P.O. Box 16858, Philadelphia, Pa. 19142.

FOR FURTHER INFORMATION CONTACT: H. Lund, Airframe Section, AEA–212, Engineering and Manufacturing Branch, Federal Building, J.F.K. International Airport, Jamaica, New York 11430; Tel. 212–995–2875.

SUPPLEMENTARY INFORMATION: There had been a report that the cyclic stick boot had been binding the stick during the operation of the helicopter. It was concluded that the forward support spring of the boot was binding on the stick's retaining bolt. An analysis concluded that the forward spring was not that essential, and the boot could be supported by the aft spring. Thus, this amendment requires the removal of the forward spring. Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended, by adding the following new Airworthiness Directive:

Boeing Vertol (Vertol): Applies to Vertol Model 107–II helicopters with pilot or copilot cyclic stick boots, P/Ns 107S2226–9, –13 or –17, certificated in all categories.

To prevent possible restriction of cyclic stick travel accomplish the following within the next 25 hours in service after the effective date of this AD, unless already accomplished.

a. Loosen the velcro tape and camloc fasteners securing the pilot and copilot cyclic stick boots, P/N 107S2226–9, –13 or –17, and remove the boots.

b. Remove the two rivets which attach the forward spring, P/N 107S2226–12, to the forward end of the boot base and discard the forward spring.

c. Install washers and new rivets to plug the resulting two empty holes in the boot base.

d. Reinstall the pilot and copilot stick boots.

e. Upon request with substantiating data submitted through an FAA Maintenance Inspector, the compliance time specified in this AD may be adjusted by the Chief, Engineering and Manufacturing Branch, FAA Eastern Region.

Effective Date. This amendment is effective May 28, 1980.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended, (49 U.S.C. 1354(a), 1421, and 1423); sec. 6(c), Department of Transportation Act, (49 U.S.C. 1655(c); and 14 CFR 11.89))

Note.—The Federal Aviation Administration has determined that this document involves a regulation which is not significant under Executive Order 12044 as implemented by Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

Issued in Jamaica, New York, on May 14, 1980.

Timothy L. Hartnett,

Acting Director, Eastern Region.

[FR Doc. 80–15831 Filed 5–23–80; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 80–EA–8, Amdt. 39–3779]

Airworthiness Directives; Piper Model PA 38–112

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final Rule.

SUMMARY: This amendment issues a new airworthiness directive, applicable to Piper PA 38–112 type airplanes, which requires a replacement of the main landing gear attach bolts. This is required to eliminate loose, bent and cracked bolts due to improper length of bolts, improper shimming and torque. The defective bolts could result in gear failure.

EFFECTIVE DATE: May 29, 1980. Compliance is required within 50 hours in service.

ADDRESSES: Piper Service Bulletins may be acquired from the manufacturer at Piper Aircraft Corporation, 820 East Bald Eagle Street, Lock Haven, Pennsylvania 17745.

FOR FURTHER INFORMATION CONTACT: C. Kallis, Airframe Section, AEA–212, Engineering and Manufacturing Branch, Federal Building, J.F.K. International Airport, Jamaica, New York 11430; Tel. 212–995–2875.

SUPPLEMENTARY INFORMATION: There have been reports of loose, bent and cracked main landing gear attach bolts on Piper Model PA 38–112 airplanes. This condition is the result of the use of improper bolt lengths, shims and bolt torque and can result in gear failure. Since this condition is likely to exist on other airplanes of the same type design, this amendment requires replacement of the main landing gear attach bolts, use of proper shims and proper bolt torque on Piper Model PA 38–112 airplanes. Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended, by adding the following new Airworthiness Directive:

Piper: Applies to Piper Model PA–38–112 Serial Nos. 38–78A0001 thru 38–78A0823, 38–79A0001 thru 38–79A1179, 38–80A0001 thru 38–80A0036 certificated in all categories.

To prevent possible loosening of the main landing gear attachment bolts accomplish the following:

a. Within the next 50 hours in service after the effective date of this AD, unless already accomplished, replace the main landing gear AN5–13A attachment bolts and AN960–15 washers in accordance with the *Instructions* section of Piper Service Bulletin 673 dated January 16, 1980, or an equivalent that must be approved by the Chief, Engineering and Manufacturing Branch, FAA, Eastern Region.

b. Upon submission of substantiating data through an FAA Maintenance Inspector, the compliance time specified in the AD may be adjusted by the Chief, Engineering and Manufacturing Branch, FAA, Eastern Region.

Effective Date. This amendment is effective May 29, 1980.

(Secs. 313(a), 601, 603, Federal Aviation Act of 1958, as amended, (49 U.S.C. 1354(a)), 1421, and 1423; sec. 6(c), Department of Transportation Act, (49 U.S.C. 1655(c)); and 14 CFR 11.89.)

Note.—The Federal Aviation Administration has determined that this document involves a regulation which is not significant under Executive Order 12044 as implemented by Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

Issued in Jamaica, New York, on May 15, 1980.

Timothy L. Hartnett,

Acting Director, Eastern Region.

[FR Doc. 80–15832 Filed 5–23–80; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 39

[Docket No. 80-WE-22-AD, Amdt. 39-3775]

Airworthiness Directives; General Dynamics Model 340 and 440 Airplanes

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) which requires inspection and eventual rework of horizontal stabilizer attach fittings on General Dynamics Model 340/440 airplanes. The AD is prompted by reports of horizontal stabilzer attach fittings fatigue cracking which could result in horizontal stabilizer failure.

DATES: Effective: May 29, 1980.

Compliance schedule—As prescribed in the body of the AD.

ADDRESSES: The applicable service information may be obtained from: General Dynamics, P.O. Box 80877, San Diego, California 92138, Attention: Mr. Larry Hayes, Manager, Product Support, Convair Division.

Also, a copy of the service information may be reviewed at, or a copy obtained from:

Rules Docket in Room 916, FAA, 800 Independence Avenue SW., Washington, D.C. 20591,

or

Rules Docket in Room 6W14, FAA Western Region, 15000 Aviation Boulevard, Hawthorne, California 90261.

FOR FURTHER INFORMATION CONTACT: Jerry Presba, Executive Secretary, Airworthiness Directive Review Board, Federal Aviation Administration, Western Region, P.O. Box 92007, World Way Postal Center, Los Angeles, California 90009. Telephone: (213) 536-6351.

SUPPLEMENTARY INFORMATION: There have been several reports of horizontal stabilizer attach fitting cracking, attributable to fatigue, on General Dynamics Model 340/440 airplanes which could result in failure to retain the horizontal stabilizer. Since this condition is likely to exist or develop on other airplanes of the same type design, an airworthiness directive is being issued which requires inspection of horizontal stabilizer attach fittings and rework of these fittings at a future date on General Dynamics Model 340/440 airplanes.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended, by adding the following new airworthiness directive:

General Dynamics: Applies to Model 340, 440 Military Models C-131D and C-131E and other military models eligible or to be made eligible for civil use under type certificate 6A6, and all such model airplanes converted to turbopropeller power, certificated in all categories.

Compliance required as indicated.

To prevent potential loss of the horizontal stabilizer, accomplish the following:

(a) Within 250 hours' additional time in service from the effective date of this AD, unless previously accomplished within the last 950 hours' time in service, conduct ultrasonic inspection of horizontal stabilizer attach fittings per paragraph D of General Dynamics Convair Service Bulletin 640 (340D) 55-3A dated November 12, 1979, (hereinafter referred to as SB 640 (340D) 55-3A). If any cracks are discovered, replace with like serviceable part prior to return to service.

(b) Within 1200 hours' additional time in service from the inspection required in paragraph (a) of this AD and thereafter at intervals not to exceed 1200 hours' time in service since the last such inspection, repeat the inspection required by paragraph (a) of this AD.

(c) Within 10,000 hours' additional time in service from the effective date of this AD install bushings in the horizontal stabilizer fitting attachment holes per paragraph D of SB 640 (340D) 55-3A and continue to inspect at 1200 hours intervals per paragraph (a) of this AD.

(d) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections required by this AD.

(e) Alternative inspections, modifications or other actions which provide an equivalent level of safety may be used when approved by the Chief, Aircraft Engineering Division, FAA Western Region.

This amendment becomes effective May 29, 1980.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); sec. 6(c) Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.89)

Note.—The Federal Aviation Administration has determined that this document involves a final regulation which is not considered to be significant under Executive Order 12044 as implemented by DOT Regulatory Policy and Procedures (44 FR 11034: February 26, 1979). In addition, the expected impact is so minimal that this action does not warrant preparation of a regulatory evaluation.

Issued in Los Angeles, Calif., on May 13, 1980.

W. R. Frehse,

Acting Director, FAA Western Region.

[FR Doc. 80-15833 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 79-EA-72; Amdt. 39-3776]

Airworthiness Directives; Piper Model PA-31T and PA-31T1;

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment issues a new airworthiness directive, applicable to Piper PA-31T and PA-31T1 type airplanes, which requires an inspection and correction where necessary of the data plate. This results from the manufacturer inadvertently causing approximately fifty-four PA-31T1 airplanes to be stamped with a PA-31T data plate. Failure to make the correction could result in some air safety applications to PA-31T1 airplanes not being accomplished on the same type airplane while identified as PA-31T.

EFFECTIVE DATE: May 28, 1980. Compliance is required as set forth in the AD.

ADDRESSES: Piper Service Bulletins may be acquired from the manufacturer at Piper Aircraft Corporation, 820 East Bald Eagle Street, Lock Haven, Pennsylvania 17745.

FOR FURTHER INFORMATION CONTACT: C. Kallis, Airframe Section, AEA-212, Engineering and Manufacturing Branch, Federal Building, J.F.K. International Airport, Jamaica, New York 11430; Tel. 212-995-2875.

SUPPLEMENTARY INFORMATION: The FAA has determined that certain Piper Model PA-31T1 airplanes have data plates which are stamped PA-31T. This could result in some air safety applications to PA-31T1 airplanes not being accomplished on the same type airplane while it is identified as a PA-31T. This amendment requires an inspection and correction where necessary, of the data plate of certain Piper Model PA-31T1 and PA-31T airplanes. Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended, by adding the following new Airworthiness Directive:

Piper: Applies to Piper PA-31T1 and PA-31T Model airplanes, Serial Nos. 31T-7804001 thru 31T-7904053, 31T-7904056, and 31T-7904057 certificated in all categories. To correct an error on the data plate, within the next 100 hours in service unless already accomplished, accomplish the following:

a. Locate the aircraft data plate (Part No. 79844-4), on the left side of the fuselage belly, just below the forward part of the cabin door.

b. Using an acceptable method of permanent marking (metal stamp, engraver, electric pencil, etc.), inscribe the numeral "1" behind "PA-31T" in the gold block in which "Model" is designated. Before Modification: "MODEL PA-31T"; After Modification: "MODEL PA-31T1".

Effective Date. This amendment is effective May 28, 1980.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, 1423); sec. 6(c), Department of Transportation Act, (49 U.S.C. 1655(c); and 14 CFR 11.89.)

Note.—The Federal Aviation Administration has determined that this document involves a regulation which is not significant under Executive Order 12044 as implemented by Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

Issued in Jamaica, New York, on May 14, 1980.

Timothy L. Hartnett,

Acting Director, Eastern Region.

[FR Doc. 80-15834 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 80-EA-4; Amdt. 39-3777]

Airworthiness Directives; Piper Model PA 38-112

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends AD 79-03-02, applicable to Piper PA 38-112 type airplanes, which required the incorporation of a kit for positive retention of the bottom rudder hinge bearing. This amendment will extend the applicability of AD 79-03-02 to all PA 38-112 up to those in which the manufacturer will incorporate the kit. This results from the discovery of additional bearings, which had been machine swaged, coming loose.

EFFECTIVE DATE: May 28, 1980. Compliance is required as set forth in the AD.

ADDRESSES: Piper Service Bulletins may be acquired from the manufacturer at Piper Aircraft Corporation, 820 East Bald Eagle Street, Lock Haven, Pennsylvania 17745.

FOR FURTHER INFORMATION CONTACT:

C. Kallis, Airframe Section, AEA-212, Engineering and Manufacturing Branch, Federal Building, J.F.K. International Airport, Jamaica, New York 11430; Tel. 212-995-2875.

SUPPLEMENTARY INFORMATION: Amendment 39-3402, (44 FR 5061, January 25, 1979), AD 79-03-02 had been issued to correct a deficiency whereby bottom rudder hinge bearings which had been hand swaged had come loose. It now appears that machine-swaged bearings may also come loose. Thus, this amendment will cover all machine-swaged bearings for which the retention kit has not been incorporated in the airplanes. Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by amending Amendment 39-3402, (44 FR 5061, January 25, 1979), AD 79-03-02, as follows:

In the applicability paragraph insert Serial Nos. 38-78A0001 thru 38-80A0063, in lieu of Serial Nos. 38-78A0001 thru 38-78A0348.

Effective Date. This amendment is effective May 28, 1980.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, 1423); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.89)

Note.—The Federal Aviation Administration has determined that this document involves a regulation which is not significant under Executive Order 12044 as implemented by Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

Issued in Jamaica, New York, on May 14, 1980.

Timothy L. Hartnett,

Acting Director, Eastern Region.

[FR Doc. 80-15835 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 79-WE-10-AD, Amdt. 39-3780]

McDonnell Douglas DC-10 Series Airplane; Airworthiness Directives

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes a currently effective airworthiness directive applicable to McDonnell Douglas DC-10 series airplanes by requiring certain design changes to wing-mounted pylons and revising the wing-pylon inspection programs. This AD is necessary to reduce the possibility of inflicting internal structural damage during maintenance operations, to ensure integrity of wing-pylon structure and to eliminate inspections shown to be redundant.

DATES: Effective May 27, 1980.

Compliance schedule—As prescribed in the body of the AD.

ADDRESSES: The applicable service information may be obtained from: McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, CI-750 (54-60).

Also, a copy of the service information may be reviewed at, or a copy obtained from:

Rules Docket in Room 916, FAA, 800 Independence Avenue SW., Washington, D.C. 20591.

or

Rules Docket in Room 6W14, FAA Western Region, 15000 Aviation Boulevard, Hawthorne, California 90261.

FOR FURTHER INFORMATION CONTACT: Jerry Presba, Executive Secretary, Airworthiness Directive Review Board, Federal Aviation Administration, Western Region, P.O. Box 92007, World Way Postal Center, Los Angeles, California 90009. Telephone: (213) 536-6351.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive requiring certain design changes and a revised wing-pylon inspection program on McDonnell Douglas DC-10 Series airplanes to supersede Amendment 39-3505 as amended by Amendment 39-3557 was published in the Federal Register at 45 FR 5741. Interested persons have been afforded an opportunity to participate in the making of the amendment.

Comments from nine persons were received, some of which indicated a lack

of familiarity with the January 1980 "DC–10 Decision Basis Summary Report" and other detailed technical material which had been included in the docket for review by all interested persons as stated in the notice.

Several comments recommended increased flexibility in the periodic inspection intervals. Comments on this subject ranged from concern that the revised inspection intervals were unduly conservative to the view that the revised inspection intervals were unduly liberal. The FAA recognizes the need for flexiblity in maintenance scheduling and accordingly has provided an option of "3600 hours' time in service or 12 calendar months, whichever occurs later," which is consistent with the rationale presented in the NPRM and supporting public documents.

Other comments were received on the general subject of the inspection program with specific regard to the absence of sampling provisions in the proposed rule. One commenter felt that the possibility of sampling would introduce safety problems. Another commenter felt that deletion of sampling was discriminatory and recommended that the inspection program revert to the original requirements of the Maintenance Review Board document on the DC–10.

The FAA did not capriciously delete sampling as an inspection technique on the DC–10 pylon. The original MRB document permitted sampling in the area of the pylon upper spar web, but good cause now exists for requiring a 100% inspection of this area, based upon service experience (See "DC–10 Decision Basic Summary Report"). It is not the intent of the FAA to rule out sampling as an acceptable inspection technique for the entire DC–10 pylon. Rather, the FAA requires 100% inspection in the certain specified pylon areas. FAA will evaluate future recommendations for modifications to the inspection program (including sampling) based upon results of these inspections and proposals submitted by the affected operators.

With regard to future maintenance schedules, paragraph (g) of the proposal provided for specific submittal to FAA of revised pylon maintenance programs, as an amendment to the operations specifications, by each carrier. Taken in conjunction with paragraph (m) of the proposal, which provides for approval of alternative inspections that will yield an equivalent level of safety, the proposal has provided for tailoring of an individual carrier's maintenance program to its service experience, routes, and other relevant factors.

Other comments offered opinions relative to FAA approval of the installation and removal of the engine and pylon as a unit. The comments generally recommended caution in granting such approval and, in one case, that such approvals should not be granted. The FAA will evaluate proposals for combined engine/pylon removal and installation and, if the necessary controls are found to exist, the practice will be approved for that particular operator at a specific facility, utilizing specific equipment, and satisfying specified personnel training requirements.

Comments were received relative to the desirability of redundancy of the load path through the aft bulkhead forward flange and redundancy of the retention of the bushing through the aft wing mounted clevis and pylon bulkhead. These matters were thoroughly discussed in the "DC–10 Decision Basis Summary Report, January 1980," Attachment 6, pages 2 through 6. The conclusion reached by the FAA is that the DC–10 satisfies the regulatory safety requirements in its present configuration in these areas. Millions of hours of service experience and exhaustive analysis have demonstrated no need to revise the regulatory requirement and have substantiated the application of the regulations to this feature of the DC–10.

One commenter stated his concern that numerous paragraphs (other than paragraph (m)), in the proposed AD, which included reference to methods to be "approved by the Chief, Aircraft Engineering Division, FAA Western Region," would represent problems of completeness and clarity to foreign operators and their civil aviation authorities. The FAA recognizes this concern and has used this language only when specific approved data and/or procedures were not yet developed. Since the issuance of the NPRM, certain data have been developed and are listed in the AD in lieu of the alternative which was the cause of concern. The FAA has eliminated the phrase wherever possible.

One commenter recommended against requiring flush-head bolt installation and incorporation of a mechanical device (intended to minimize the possibility of bulkhead lug to clevis assembly contact) because accepted aircraft design practice does not include a requirement for the tolerance of abusive maintenance and inadequate inspection practices. This is generally true, however, prudent application of lessons learned from this experience weighs heavily toward incorporation of these features. The added measure of safety referred to in the NPRM by these changes is, in the judgment of the FAA, the minimum level of safety appropriate in light of service experience.

In the interim period since the issuance of the NPRM, some data have been developed and/or updated by the manufacturer. Consequently, some additional prescriptions for acceptable methods of accomplishment have been included as clarifying changes, where appropriate. These changes are not substantive.

Other comments were received which were previously discussed in the "DC–10 Decision Basis Summary Report, January 1980," which the commenter apparently had not reviewed prior to submitting comments.

Comments were received on typographical errors and recommendations were received for clarifying editorial changes, which have been incorporated. No substantive comments were received addressing the economic impact of the proposal.

Copies of all comments received on this proposal have been placed in public dockets, available for inspection at both the FAA's Western Region Headquarters, 15000 Aviation Boulevard, Room 6W14, Hawthorne, California, and FAA Headquarters, 800 Independence Avenue, SW., Room 916, Washington, D.C. Copies of the following materials, which form a substantive part of the decision basis for this rulemaking action, are also available for review in the docket:

(1) DC–10 Wing Pylon Damage Tolerance Study (2 volumes, Report Nos. MDC–J–8543 and MDC–J–8545);

(2) Final Report of the DC–10 Pylon Damage Tolerance Team;

(3) Comments by Science Advisory Group on Proposed Amendments to Airworthiness Directives for DC–10 Aircraft and Related Supporting Documents, by Raymond L. Bisplinghoff, et al.;

(4) DC–10 Wing Pylon Upper Spar Web Damage Analysis;

(5) Summary Report, DC–10 Decision Basis, January 1980.

After careful review of all available data, including the data and comments noted above, the FAA believes that sufficient evidence exists in the public interest in aviation safety to adopt the rule with the changes noted above.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended, by adding the following new airworthiness directive:

McDonnell Douglas: Applies to Model DC-10-10, -10F, -30, -30F, and -40 series airplanes, certificated in all categories.

Compliance required as indicated.

To ensure integrity of the wing engine pylon structure and attachment, accomplish the following on both the right and left wing:

(a) At each pylon removal and installation after the effective date of this AD, remove and install the engine and pylon separately unless removal or installation, or both, as an assembly is in accordance with a method approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(b) At the next pylon reinstallation after the effective date of this amendment, unless already accomplished, install two flush-head bolts in place of the two raised head bolts adjacent to the pylon aft bulkhead upper flange centerline, in accordance with McDonnell Douglas DC-10 Service Bulletin 54-78 dated April 2, 1980.

(c) At each pylon reinstallation after June 30, 1980, protect the pylon aft bulkhead lug from contact with the clevis to wing attach bolt heads in accordance with a method approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(d) Before further flight following any pylon reinstallation after the effective date of this AD, (1) inspect the aft pylon bulkhead in accordance with McDonnell Douglas DC-10 Nondestructive Testing Manual, Chapter 54-10-11, pages 634 and 634A, dated December 1, 1979; (2) inspect the pylon aft spherical bearing and attaching hardware to verify security of nut and bolt; and (3) inspect torque stripe for alignment. For pylons installed prior to June 30, 1980 on which paragraph (c) of this AD was not accomplished, repeat the inspection within the next 300 hours' time in service after the reinstallation inspection, and again within the next 600 hours' time in service following the second inspection.

(e) At next pylon reinstallation after the effective date of this AD or before the accumulation of 48,000 hours' total time in service, whichever comes sooner, unless already accomplished, install steel thrust links in place of titanium thrust links on all DC-10-10, -30, and -40 series aircraft in accordance with Part 2 of McDonnell Douglas Service Bulletin (SB) 54-47, dated August 18, 1975 (DC-10-30 and DC-10-40 Series), or McDonnell Douglas Service Bulletin 54-82, dated May 15, 1980 (DC-10-10 Series).

(f) Before the accumulation of 3,600 hours' total time in service, or within the next 3,600 hours' time in service or twelve calendar months, whichever comes later, since the last such inspection on airplanes with more than 3,600 hours' total in service as of the effective date of this AD, and thereafter at intervals not to exceed 3,600 hours' times in service or twelve calendar months since the last inspection, inspect as follows:

1. Inspect wing and pylon attach fitting lugs in accordance with Part 2, paragraph C(1), of McDonnell Douglas Service Bulletin SB 54-74, dated December 21, 1979 (hereinafter referred to as SB 54-74).

2. Visually inspect the upper surface of pylon upper spar in accordance with Part 2, paragraph G, of SB 54-74.

3. Visually inspect lower surface of upper spar and spar cap angles in accordance with Part 2, paragraph M, of SB 54-74.

4. Inspect pylon in accordance with DC-10 Maintenance Manual, Chapter 5-51-08, dated April 1, 1980. In addition, inspect the pylon aft spherical bearing and attaching hardware to verify security of nut and bolt; inspect torque stripe for alignment.

5. Perform an in situ X-ray or other nondestructive inspection of titanium thrust links to ensure integrity, in accordance with a method approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(g) Within the next 30 days following the effective date of this AD, submit a pylon maintenance program as an amendment to the operations specification, to the assigned FAA Maintenance Inspector for approval, specifying that before the accumulation of 20,000 hours' time in service or within the next 20,000 hours' time in service since the last inspection, whichever occurs sooner, and thereafter at intervals not to exceed 20,000 hours' time in service since the last inspection, the operator will, at a minimum—

1. Inspect pylon aft bulkhead visually in accordance with Part 2, paragraphs E and F of SB 54-74, and by eddy current in accordance with DC-10 Nondestructive Testing Manual, pages 634 and 634A, dated December 1, 1979.

2. Visually inspect front spar bulkhead in accordance with Part 2, paragraph H of SB 54-74.

3. Inspect wing front spar attach fitting (foot stool) in accordance with Part 2, paragraph L of SB 54-74.

4. Inspect lower forward spherical bearing in accordance with Part 2, paragraph I of SB 54-74.

5. Inspect upper forward sphercial bearing plug assembly in accordance with methods specified in Part 2, paragraph J of SB 54-74 for both steel and titanium plugs.

6. Inspect thrust link installations in accordance with Part 2, paragraph C(2) of SB 54-74.

7. Inspect the aft spherical bearing as follows:

i. Remove aft spherical bearing through bolt. Magnaflux bolt and visually inspect inner bore of bushing in situ. Visually inspect forward and aft surfaces of spherical bearing for cracks using 10X (power) glass (or equivalent). Reinstall through bolt.

ii. Verify that torque of through bolt is 1200 to 1300 inchpounds.

iii. Inspect aft spherical bearing forward face/clevis clearance.

iv. Torque stripe nut to bolt.

8. Ultrasonically inspect the bulkhead lug and wing clevis to wing attachment including bolts in accordance with DC-10 Nondestructive Testing Manual, Chapter 54-10-11, pages 635, 636, 637, 638, 638A, 638B, 651, 652, 654 and 655, as applicable dated December 1, 1979.

9. Perform an X-ray or other in situ inspection of steel thrust links to ensure integrity, in accordance with a method approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(h) After a pylon has been subjected to vertical or horizontal misalignment, or both (e.g. during maintenance), before further flight, inspect in accordance with DC-10 Nondestructive Testing Manual, Chapter 54-10-11 pages 634 and 634A dated December 1, 1979.

(i) After each installation of a pylon with a titanium upper forward spherical bearing plug, after 200 hours' time in service from time of installation and not later than 400 hours' time in service after installation, ultrasonically inspect titanium plug in place in accordance with McDonnell Douglas Nondestructive Testing Manual 54-10-11, pages 628, 628A, 628B and 628C dated December 1, 1979.

(j) Inspect pylon for structural integrity in accordance with McDonnell Douglas DC-10 Maintenance Manual, Chapter 5-51-08 dated April 1, 1980 prior to further flight after events producing high pylon loads including, but not limited to:

1. Hard or overweight landings,

2. Severe turbulence encounters,

3. Engine vibration which requires engine removal or critical engine failure, or both,

4. Ground damage (workstands, etc.),

5. Compressor stalls requiring engine removal,

6. Excursions from the runway of a nature that might have imposed loadings more severe than those normally encountered on the runway.

(k) Whenever fasteners are replaced as a result of the inspections specified in SB 54-74, Part 2, paragraph G, prior to installing new fasteners, inspect the holes and the area around adjacent fasteners (without removing fasteners) for cracks using eddy current or equivalent NDT methods.

(l) All discrepancies found as a result of inspections required by this AD which exceed limitations specified in FAA approved data must be corrected prior to further flight.

(m) Alernative inspections, modifications or other actions which provide equivalent level of safety may be used when approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(n) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections required by this AD.

(o) Report results of all inspections to the assigned FAA Maintenance Inspector within 24 hours of accomplishment in the following format:

"N" Number, hour's time in service at inspection, pylon number, results of inspection by specific paragraph and subparagraph of this AD. In reporting be as specific as possible to identify location and size of crack, or specific location of discrepant fastener, etc. List part numbers.

Note.—The Federal Aviation Administration has determined that this document involves a final regulation which is not considered to be significant under Executive Order 12044, as implemented by DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). In addition, the expected impact is so minimal that this action does not warrant preparation of a regulatory evaluation.

This supersedes Amendment 39-3513 (44 FR 45375), AD 79-15-03, as amended by 39-3557 (44 FR 53735).

Issued in Los Angeles, Calif., on May 16, 1980.

W. R. Frehse,

Acting Director, FAA Western Region.

[FR Doc. 80-15983 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

[Docket No. 80-CE-18-AD, Amdt. 39-3782]

39 CFR Part 39

Cessna Model 150F, 150G, 150H, 150J, 150K, 150L, 150M, A150K, A150L, A150M, F150F, F150G, F150H, F150J, F150K, F150L, F150M, FA150K, FA150L, FRA150K, FRA150L, FRA150M, 152, A152, F152, and FA152 Airplanes; Airworthiness Directives

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new Airworthiness Directive (AD), to supersede AD 78-07-10, which requires repetitive inspection of NAS 1068A4 nutplates on certain Cessna Model 150F, 150G, 150H, 150J, 150K, 150L, 150M, A150K, A150L, A150M, F150F, F150H, F150J, F150K, F150L, F150M, FA150K, FA150L, FRA150K, FRA150L, FRA150M, 152, A152, F152, and FA152 airplanes until replaced with suitable nuts. The AD is needed to prevent a possible looseness and/or separation of the vertical or vertical and horizontal tail assemblies from the airplane, which would have an adverse effect on aircraft controllability and safety of flight.

EFFECTIVE DATE: June 2, 1980.

COMPLIANCE: As prescribed in the body of the AD.

ADDRESSES: Cessna Single Engine Service Information Letter SE79-49, Revision #1, dated April 28, 1980, applicable to this AD, may be obtained from Cessna Aircraft Company, Marketing Division, Attention: Customer Service Department, Wichita, Kansas 67201; Telephone (316) 685-9111. Copies of the service letter are contained in the Rules Docket, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106, and at Room 916, 800 Independence Avenue, SW., Washington, D.C. 20591.

FOR FURTHER INFORMATION CONTACT: Douglas W. Haig, Aerospace Engineer, Aircraft Certification Program, Room 238, Terminal Building 2999, Mid-Continent Airport, Wichita, Kansas 67209, telephone (316) 942-4219.

SUPPLEMENTARY INFORMATION: This amendment supersedes Amendment 39-3174, AD 78-07-10 (43 FR 14958, 14959), applicable to certain Cessna 150, A150, 152, A152, F150, FRA150, FA150, F152 and FA152 airplanes, which currently requires a one-time inspection of NAS 1068A4 nutplates. Four of these nutplates are used in the attachment of the vertical stabilizer to the horizontal stabilizer and four more are used in the attachment of the horizontal and vertical stabilizer assembly to the fuselage. The one-time inspection was required as the result of cracked NAS 1068A4 nutplates. Subsequent to the issuance of AD 78-07-10, review of Malfunction or Defect (M or D) Reports revealed that the aforementioned AD was not accomplishing its intended purpose. There was a wide scatter factor relative to the time-in-service that nutplates were cracking. Cracked nutplates were found on repetitive inspections not required by AD 78-07-10 and, also, on airplanes outside the serial range listed in the AD. The manufacturer recognized this problem by issuance of Service Information Letters SE79-49, September 24, 1979, and SE 79-49, Revision #1, dated April 28, 1980. These letters recommend a 100-hour time-in-service repetitive inspection and increases applicability to include all models from 1966 through the current production model year. Service Letter SE78-1 dated January 30, 1978 (the basis for AD 78-07-10) was applicable only to the 1974 through 1978 model years.

Since this condition is likely to exist or develop repetitively on airplanes to which AD 78-07-10 applies, and other airplanes of the same type design, the FAA is issuing an AD superseding AD 78-07-10 and requiring repetitive inspection and/or replacement of the NAS 1068A4 nutplates on certain serial numbers of Cessna 150, A150, 152, A152, F150, FA150, FRA150, F152 and FA152 airplanes. The FAA has determined that there is an immediate need for a regulation to assure safe operation of the affected airplanes and to provide affected owners/operators early notification of the opportunity to have the optional nuts installed at the first repetitive inspection.

Since a situation exists that requires the immediate adoption of this regulation, notice and public procedure under 5 U.S.C. 553(b) is impracticable and contrary to the public interest and good cause exists for making the amendment effective in less than (30) days after the date of publication in the Federal Register.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new Airworthiness Directive.

Cessna: Applies to the following models and serial number airplanes certificated in all categories:

Models and serial Nos.

150F, 15061533 through 15064532
150G, 15064533 through 15067198
150H, 15067199 through 15069308
150J, 15069309 through 15071128
150K, 15071129 through 15072003
150L, 15072004 through 15075781
150M, 15075782 through 15079405
A150K, A1500001 through A1500226
A150L, A1500227 through A1500523
A150M, A1500524 through A1500734
152, 15279406 through 15284541
A152, A1520735 through A1520943
F150F, F150-0001 through F150-0067
F150G, F150-0068 through F150-0219
F150H, F150-0220 through F150-0389
F150J, F150-0390 through F150-0529
F150K, F15000530 through F15000658
F150L, F15000659 through F15001143
F150M, F15001144 through F15001428
FA150K, FA1500001 through FA1500061
FA150L, FA1500062 through FA1500120
FRA150L, FRA1500121 through FRA1500261
FRA150M, FRA1500262 through FRA1500336
F152, F15201429 through F15201803
FA152, FA1520337 through FA1520372

Compliance: Required as indicated unless already accomplished.

To detect cracked NAS 1068A4 nutplates which, if allowed to go undetected, could result in separation of the vertical or vertical and horizontal tail assembly from the airplane, within 100 hours-time-in-service after the effective date of this AD, and every 100 hours time-in-service thereafter, accomplish the following:

(A) Using a suitable light and mirror visually inspect the eight NAS 1068A4 nutplates installed on the Part Number 0432004-9 vertical fin aft attach bracket for cracks in the threaded part (nut body) and/or base of the nutplate and replace any cracked nutplates prior to further flight.

(B) Compliance with this AD is no longer required if the NAS 10684A nutplates are replaced with AN365-428, M520365-428, MS21042L4 or MS21044N4 nuts.

(C) Any equivalent method of compliance with this AD must be approved by the Chief, Aircraft Certification Program, Room 238, Terminal Building 2299, Mid-Continent Airport, Wichita, Kansas 67209.

Note.—Cessna Single Engine Service Information Letter SE79-49, Revision No. 1, dated April 28, 1980, pertains to the subject.

The AD supersedes AD 78-07-10, Amendment 39-3174 (43 FR 14958, 14959). This amendment becomes effective June 2, 1980.

(Secs. 313(a), 601, 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); sec. 6(c) Department of Transportation Act (49 U.S.C. 1655(c)); sec. 11.89, Federal Aviation Regulations (14 CFR 11.89))

Note.—The FAA has determined that this document involves a regulation which is not significant under Executive Order 12044, as

implemented by Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the final evaluation prepared for this document is contained in the docket. A copy of it may be obtained by writing to John L. Fitzgerald, Jr., Attorney, Office of the Regional Counsel, Room 1558, Federal Aviation Administration, Central Region, 601 East 12th Street, Kansas City, Missouri 64106, telephone (816) 374-5446.

Issued in Kansas City, Missouri, on May 16, 1980.

Paul J. Baker,

Director, Central Region.

[FR Doc. 80-15982 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 159

[Docket No. 20200; Amdt. 159-18]

Solicitation and Leafletting Procedures at National and Dulles International Airports

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment regulates solicitation of funds and distribution of literature by non-profit organizations at National and Dulles airports. The amendment promotes the efficient use of these facilities and the security of patrons using the terminals without infringing upon the rights of individuals who choose to use the airport for constitutionally protected activity. Title V of Public Law 96-193 enacted February 18, 1980 directed F.A.A. to promulgate regulations to control solicitation activity at Washington National and Dulles Airports.

EFFECTIVE DATE: July 28, 1980.

FOR FURTHER INFORMATION CONTACT: Edward S. Faggen, Legal Counsel, AMA-7, Washington National Airport, Hangar 9, Washington, D.C. 20001, telephone: (703) 557-8123.

SUPPLEMENTARY INFORMATION:

Discussion of the Final Rule

A. Background

By a recent legislative enactment, Congress has directed FAA to promulgate regulations to control solicitation activity at Washington National and Dulles Airports. Title V of Pub. L. 96-193 enacted February 18, 1980 provides:

Section 501(a) The Administrator of the Federal Aviation Administration (hereinafter referred to as the "Administrator") shall, within 90 days after the date of enactment of this Act, promulgate regulations for airports operated by the Administration to regulate the access to public areas by individuals or by religious and nonprofit organizations (as defined in section 501(c)(3) of the Internal Revenue Code of 1954) for the purpose of soliciting funds or distributing materials.

(b) In promulgating regulations under this section the Administrator shall consider requiring any individual or organization described in subsection (a) to submit an application for a permit to engage in the soliciting of funds or the distribution of materials. In considering such an application the Administrator may require that—

(1) a responsible individual representative of the applicant shall be designated to represent the organization;

(2) each individual participating in any solicitation or distribution will display a proper identification approved by the Administrator;

(3) the number of individuals engaged in any solicitation or distribution at any one time shall not exceed a reasonable number, in keeping with the need for free movement in and operation of the airports as provided for by the permit;

(4) the solicitation or distribution be confined to limited areas and times; and

(5) no individual or organization which holds a permit under this section shall be permitted to—

(A) use sound amplification or display signs (other than signs approved by the Administrator);

(B) intentionally interfere with users of the airport;

(C) engage in the use of indecent or obscene remarks or conduct; or

(D) engage in the use of loud, threatening, or abusive language intended to coerce, intimidate or disturb the peace.

(c)(1) The Administrator shall consider requiring that a copy of a permit (if such is required) be conspicuously posted in the area in which any solicitation or distribution is permitted.

(2) The Administrator shall consider whether revocation of approval for any permit if required and approved under this section should occur for any violation of any rule or regulation promulgated hereunder.

(d) Regulations intended to be promulgated under this section shall be submitted to Congress within 30 days after the date of enactment of this Act.

In recent years it has become a common practice for various religious and non-profit organizations to use commercial airports as a forum for the distribution of literature, the solicitation of funds, the proselytizing of new members, and other similar activities. Washington National and Dulles International Airports are no exception to this trend. The airports are owned by the United States Government and large portions of the airport buildings were designed for and are open to the general public. Last year more than 18 million passengers passed through the terminal buildings on their way to and from air transportation. There is a considerable amount of social and commercial interchange in the terminals and, in many respects, the terminals are like any other public thoroughfare where there is no question that the Constitutional guarantees of freedom of speech, the exercise of religion and the right to peaceable assembly apply. These activities enjoy the protection of the First Amendment, and they may not be regulated by airport authorities in the same manner as commercial activity.

However, the absence of regulation has led to situations where those soliciting money or leafletting have caused or contributed to congestion in the terminals and obstruction of travelers. At National Airport, and at Dulles Airport during the peak hours of operation, the airport terminals, sidewalks and passageways are extremely congested. At National the design capacity of the terminal is greatly exceeded on a daily basis. When congestion occurs at or near points where the free flow of traffic is essential to the airport's operation, the congestion causes inconvenience to the traveling public and an interference with efficient airport operation.

Currently, there is no regulation that even limits the number of solicitors or leaflettors at the ticket counters, baggage claim areas and other areas where travelers must attend to the business which brought them to the airport. Nor is there any prohibition on the places where soliciting or leafletting activity could occur, such as near the top of staircases or escalators, at restroom entrances, doorways and other areas where such activity causes unsafe conditions as well as inefficient airport operation. Furthermore, there is no regulation which prohibits solicitation or leafletting from travelers who are in line or otherwise conducting their business at the airport. Finally, there is no requirement that solicitors identify themselves to the airport officials and to the public or that he or she indicate that he/she has the authority to represent the cause for which money is sought.

Another disturbing aspect of soliciting funds in the terminals has become apparent to FAA. Numerous written complaints have been received by the FAA concerning incidents in which airport patrons or tenants have allegedly been subjected to fraud, harassment, verbal abuse, intimidation and embarrassment. People standing in line or otherwise waiting to conduct their business at the airport find this activity to be particularly objectionable because they cannot avoid the solicitor by choosing to forego their purpose for being at the airport. Therefore, they may constitute a captive audience to behavior they find objectionable. On the other hand, there have been complaints

to FAA by representatives of groups peaceably soliciting funds. They claim to have been harassed by employees or others using the airport. There have been several instances of assault or alleged assault and there have been complaints against alleged deceptive practices of solicitors who intentionally conceal their organization's identity or fail to make change to a contributor promptly or accurately.

As proprietor of the Airport, FAA has the authority to prescribe rules of conduct to protect airport patrons and efficient operations of the airport. The FAA's authority to operate National and Dulles Airports is broad. Congress has charged FAA with "the control over and the responsibility for, the care, operation, maintenance, improvement and protection of the airport," together with the powers to make and amend rules and regulations as are necessary to the proper exercise of this control and responsibility (54 Stat. 688; 64 Stat. 771). The FAA has, by regulation, exercised control over all commercial activity that occurs at the Metropolitan Washington Airports. No business is conducted, including advertising, or space leased except upon the terms and conditions prescribed by the Director of Metropolitan Washington Airports (14 CFR 159.91(a)). Usually, these terms and conditions are set forth in a contractual form that specifically describes the business to be allowed, its location and duration. The number of such concessions or other businesses and the nature of the business are controlled by the FAA, Director of Metropolitan Washington Airports, to meet the needs of the airports and the traveling public.

The FAA also has the statutory authority to police the airports to protect life and property (61 Stat. 94; 64 Stat. 772) Under this authority, FAA has enacted regulatory "rules of conduct" (14 CFR 159.71 to 159.111) and has deployed a police force and fire department. Its police powers are no less than that of a municipality if such municipality were the airport proprietor. While on the airport, the public looks only to the Federal Government, acting through the FAA, for protection of its health and welfare interests.

Although the FAA has possessed the authority, its regulations of "conduct" on the airport have not been addressed in any detail to the solicitation of funds or the distribution of literature on the airport by individuals or organizations acting in a noncommercial capacity. The number of solicitors on the airport, the locations within the terminals, and the manner in which they solicit money from the traveling public have not been regulated by the FAA. The existing regulation, 14 CFR 159.91(b) merely proscribes the "solicitation of alms" without the permission of the Airport Manager. This is deemed inadequate to meet the standards of the First Amendment.

In view of the congestion and other operational problems, the repeated incidents in the terminals, the legislative expression of concern and the mandate to FAA to regulate the access to public areas by individuals or organizations for the purpose of soliciting funds or distributing literature, FAA has decided to establish this regulation. Under the regulation a reasonable limitation is placed on the time, place and manner of soliciting and leafletting in the National and Dulles Airport Terminals.

FAA recognizes that the soliciting of funds for religious purposes and the distribution of literature are protected under the First Amendment of the Constitution. In the area of First Amendment freedoms, including the constitutionally protected forms of solicitation, the touchstone of regulation must be precision. Regulations will not offend the Constitution if they regulate only the time, place and manner of expression, are narrowly drawn to protect only a compelling governmental interest, and are not subject to discretionary administration by officials. Any procedure which allows the airport officials wide, unbounded discretion in granting or denying permits is constitutionally questionable, because it would permit the airport to base its determination on the content of the ideas sought to be expressed.

FAA has no interest in regulating the ideas disseminated at the airport, and has no intention of regulating based on the content of the message or the cause that a solicitor supports. Also FAA has no intention of regulating in such a way as to relegate solicitors to a corner or to areas or to times of day that would deny them access to the great majority of airport users.

FAA is concerned, first, that the number of solicitors or distributors of literature not exceed a number which would aggravate existing congestion, and that such activity not be conducted at points in the terminal that are critical to airport efficiency and safety or within areas leased for the quiet enjoyment of an airport tenant. Second, FAA is concerned that those who solicit money or distribute literature in the terminal not do so for commercial purposes. It is essential to proper airport administration and operation that business activities be conducted on the airports only with the permission of the airport managers. Third, FAA expects those who solicit money from the public for non-commercial purposes to identify themselves and their cause, not for approval by the FAA but rather to provide the public this minimal assurance that it will know who is soliciting and why. Fourth, as the entity responsible for public health and welfare on the airports, FAA expects solicitors not to engage in particularly offensive, deceptive, or otherwise egregious activity. These are the legitimate, compelling proprietary and governmental interests that FAA seeks to protect by regulation. The FAA intends to impose only the least restrictive regulations on constitutionally protected activities that is necessary to protect these interests.

With this as its objective, FAA has identified those points on the airport that are critical to efficient and safe operation. These are the ticket counters, baggage claim areas, departure check in counters, departure gate lounge, anti-hijack security screening points, restroom facilities, staircases, escalators, elevators, doorways or entrance ways, and points where motor vehicles load or unload occupants and baggage. This regulation prohibits solicitation and distribution of literature within ten feet of these precisely identifiable points and from the people waiting in line to conduct business at these points. Ten feet is a readily identifiable standard, and provides the maximum freedom of movement to leaflettors and solicitors consistent with the rights of others using the airports. This regulation also prohibits leafletting and solicitation in premises leased for the exclusive use of a concessionaire.

This leaves large portions of the public lobbies and lounges, through which virtually all users of the airport pass, available to solicitors and leaflettors. FAA commissioned a study of the pedestrian traffic flow in the terminals to identify those areas that are susceptible to congestion if soliciting and leafletting occur or occur in too great a magnitude. On the basis of this study FAA identified the areas in which a certain level of soliciting and leafletting will not cause unacceptable congestion or an unsafe condition, and the maximum number of persons conducting these activities that should be allowed in each of the identified areas. Establishment of area restrictions is well within the airport proprietor's rights if there is a demonstrable and substantial relationship between the restriction and the valid interest of promoting efficient and safe use of the facilities.

The study, which was conducted by an independent consultant, used as data the layout of the terminals and several traffic counts conducted in early March 1980, a period when air traffic was well below peak levels. The analysis of the data was accomplished in two stages. First, standard air terminal planning factors were applied to figures representing the size of terminal facilities (e.g., linear feet of ticket counter) and the mean traffic flow past each facility.The result is a distance in feet from each such facility required for minimally adequate public access to that facility. From these figures, a diagram of each major terminal area was developed, indicating areas in which solicitation could be conducted with the least disruption of public business and travel. Second, the effect of introducing various numbers of solicitors into these open areas was calculated. This analysis identified the number of solicitors who could be accommodated in each area without an unaceptable level of obstruction to the flow of terminal traffic.

The study referred to *Pedestrian Planning and Design*, by John J. Fruin, a standard reference for public walkway planning. Fruin divides pedestrian flow into six categories or levels of service, A through F. Using this scale during peak hours the level of service at National is C (15–25 square feet per person), and at Dulles is D (10–15 square feet per person). This means that there is a high probability of conflict in moving requiring frequent adjustment of speed and direction to avoid contact (C level of Service). The D level severely restricts movement and there is multiple conflicting movements. FAA will allow the highest number of solicitors without lowering the level of service to D and E.

The consultant's recommendations concerning the areas in which soliciting and leafletting should be permitted, and the number of permits to be issued for those activities, are incorporated in the proposed regulation, with one exception. The study results indicated that no solicitation should be permitted in the National Airport main terminal concourse. This is a heavily trafficked area and the area most frequently used by solicitors. In the interest of permitting some level of solicitation in this area, FAA has designated a maximum of two solicitors to be allowed in a certain portion of the area. The FAA will monitor this activity and should it present an unaceptable obstacle to traffic matters, FAA will propose to modify the regulation.

At Dulles Airport a limited number of permits (7) will be issued only between 4:00 p.m. and 8:00 p.m. each day, in view of the marked peaking characteristics of traffic at that terminal. Area and numerical restrictions are inapplicable at all other times, although the permit requirements described below will apply at all times.

Each person conducting leafletting and soliciting activity will be required to obtain and display a permit. The standards for issuing such permits shall be simple and objective. Airport officials will not have the discretion to deny a permit to those who are soliciting for non-commercial purposes or distributing literature of any non-commercial nature, except in precisely defined situations.

Permit systems that protect a legitimate governmental interest, and which are administered in accordance with narrowly drawn, precise and objective standards, are clearly allowable. The Supreme Court has stated that without doubt government "may protect its citizens from fraudulent solicitation by requiring a stranger in the community, before permitting him publicly to solicit funds for any purpose, to establish his identity and his authority to act for the cause he purports to represent. The State is likewise free to regulate the time and manner of solicitation generally, the interest of public safety, peace, comfort or convenience." (*Cantwell* v. *Connecticut*, 310 U.S. 296, 306, 1940).

Under the proposal a permit will be issued by Airport Management immediately upon completion of the application provided that all available permits have not been distributed to other applicants. Permits will be issued on a first come/first serve basis. Permits will be good for two days to assure an adequate turnover in the permits while not limiting the holder to what may be an unduly brief authorization. Daily permits are administratively burdensome to the Airport personnel. Conversely, issuing permits with overly long duration may result in perpetuating certain groups or solicitors and unreasonably excluding others.

An application for a permit to distribute written or printed matter without charge or without otherwise soliciting funds, will require only the applicant's oral request for a leafletting permit.

An application for a permit to solicit contributions will require the applicant's identity, a statement that the applicant's activity is being conducted for non-commercial purposes, and certain other information intended to provide minimal public protection from fraudulent solicitation without infringing on protected activities. First, the application will require the identification of the organization which the applicant represents, and a letter or other evidence that the applicant is authorized to represent that organization. An individual need not be a member of an organization to solicit on its behalf. Second, the application will require the name and title of the person in that organization who will bear the responsibility for the applicant's activity at the airport.

Finally, the solicitor will be required to submit a statement of the organization's status as a religious, political, or charitable or public interest organization. If the applicant claims that the organization is either religious or political in nature, a statement to that effect, and nothing more, will be required. Applicants to solicit on behalf of charitable, scientific, educational or other public interest organizations will be required to submit a statement that the Internal Revenue Service has determined the organization to be eligible for tax-exempt status under 26 U.S.C.A. Sections 501(c)(3), (c)(4) or (c)(5). Applicants for organizations which have an application for such status pending may, alternatively, submit a statement to that effect. Section 501(c)(3) addresses the tax-exempt status of religious, educational, charitable, scientific, testing for public safety, fostering of certain amateur sports competition, and prevention of cruelty to children or animals organizations. Section 501(c)(4) pertains to civic leagues, social welfare organizations, and local associations of employees. Section 501(c)(5) covers labor, agricultural, and horticultural organizations.

Regulation of charitable solicitation at the airports for the protection of the public is well within FAA's regulatory and police powers. The IRS determination of tax-exempt status is used only because it constitutes an objective determination of whether an organization is commercial or non-commercial, i.e. whether or not the organization primarily benefits a charitable or public interest which is different from that of the organization's owners and management. The determination is easy to obtain if the organization has not already done so, and is minimally restrictive. (More than 200,000 organizations qualified for Section 501(c)(3) status alone as of October 1978.) Additionally, the determination provides an objective criterion for issuance of a solicitation permit by airport officials on a ministerial, non-discretionary basis. Similar documentation is not required of religious or political organizations in

consideration of the special constitutional deference to such activities, particularly religious solicitation, and the absence of appropriate documentation for political organizations.

Alternatively, an applicant representing a charitable organization may submit a statement that the organization is registered with the Virginia Administrator of Consumer Affairs in accordance with Section 57–49, Virginia Annotated Code (1978 Cumulative Supplement), "Registration of Charitable Organizations".

B. Comments Received

FAA received 15 comments on the NPRM (45 FR 20424). The proposal was favored by the individual air carriers who commented and by the Air Transport Association. While expressing support for the proposal, these commenters favored additional or more stringent requirements on solicitors and leaflettors. It was suggested that non-commercial activity be prohibited within 15 feet, not 10 feet as proposed, from critical points at the airport and lines at these points, that the regulations clarify the rights of tenants to regulate access to those areas under their exclusive control, and that solicitors pay a space rental and clean up fees the same as any business on the airports. Individuals, presumably travelers who use the airports, commented in favor of the proposal expressing the views that solicitors are "a nuisance and an aggravation to travelers."

Comments were received from organizations who regularly solicit for money at airports and from organizations concerned about the preservation of civil liberties. Many of these comments focused on significant constitutional issues raised by the FAA's proposal. While their comments were critical of various aspects of the proposal, several commenters acknowledged that FAA drafted the NPRM with careful attention to the First Amendment rights of individuals. The comments received have been helpful and the legal issues raised by the comments have prompted further revisions to the proposal, as discussed below.

In the final rule the FAA has endeavored to be attentive to the First Amendment rights of individuals who use the airports as a forum for the expression of ideas and solicitation of funds as well as responsive to its duties as the airport proprietor.

C. Specific Comments

Noncommercial Activity. The definition of non-commercial activity was criticized as vague and unprecise so as to cause individuals wishing to engage in such activity at the airports to guess whether their activity was lawful. The NPRM stated "commercial activity" means activity undertaken for profit including the sale, provision, advertisement or display of goods or services (Proposed Sec. 159.91(b)). FAA regulations have always provided that no commercial activity may take place on the airport without the approval of, and under terms and conditions prescribed by the airport manager. This is continued under the adopted rule.

As proposed in the NPRM § 159.93(b)(1) requires each person conducting "non-commercial activity" to hold a permit issued by the Airport Manager. Non-commercial activity was defined as "the following activity:

1. The distribution of printed matter to the general public, and
2. The solicitation of funds from the general public,

undertaken not for profit but for *philanthropic, religious, charitable, benevolent, humane, public interest* or *similar purposes.*"

No definition was provided for the *underscored* phrases. One commenter believes these phrases to be vague. FAA did not intend these phrases to be a limitation on who can conduct non-commercial activity on the airport. These phrases were used to better convey the difference between the commercial and non-commercial activity. For regulatory purposes the clearest definition of non-commercial activity, in view of the definition of commercial activity, is simply activity undertaken not for profit. This definition is adopted and the *underscored* phrases are not in the final regulation.

Another aspect of the proposed non-commercial activity definition that was criticized as constitutionally infirm is the provisions in § 159.93(a)(1):

provided, that if written or printed matter is for sale on the airport by a commercial vendor, its sale by any person will be treated as a "commercial activity".

This proposal was designed to protect vendors who pay for the privileges of selling printed matter at the airport from the competition by those who would sell the same printed matter, but have no overhead costs to the airport. Several commenters objected to protection of commercial facilities by imposing a restriction on the sale of religious non-commercial printed matter. Furthermore, the regulation creates a situation by which airport concessionaires could legally prevent non-commercial distribution of printed matter merely by placing that same literature for sale in their concessions. Because of these concerns, on balance, there is not at present a sufficiently compelling interest to warrant the promulgation of this aspect of the regulation. Therefore the portion of § 159.93(a)(1) quoted above will not be adopted in the final regulation.

The portion of § 159.93(a)(1) that makes the distribution of items or material other than printed matter a commercial activity will be adopted as proposed. This is not adopted to protect concessionaires but to provide airport management with control over the sale of trinkets, candies, and other such items in the terminal. Such items have no inherent message value and their sale or distribution does present airport management with litter and space utilization problems. FAA believes that it has a legitimate and compelling proprietary interest in determining where and what kind of trafficking of goods occurs on the airport.

Permit System

One commenter expressed as a general rule that no license or permits should be required at all for leafletting or solicitation of funds, and the mere fact that such activities may contribute to congestion of public areas is not a sufficient reason to justify such a requirement.

FAA respectfully disagrees. It has a statutory duty to maintain and operate the airports. Furthermore, FAA has the right to impose reasonable time, place and manner restrictions on the exercise of leafletting and soliciting activity in the airports if this would further a compelling governmental interest. The interests in this case, as stated in the NPRM, include a concern that the number of solicitors or distributors not exceed a number which would aggravate the already existing serious congestion at the airport. The purpose for which the terminal was built and maintained is to process and serve air travelers efficiently. FAA has studied the flow of traffic through the airport terminals. We employed traditional airport terminal planning factors, i.e., factors used to judge the efficiency of how terminal space serves the number of users. These planning factors have been used consistently for National and Dulles Airports and were not newly created for this study of passenger flow. The resulting study shows a clear need to limit the number of solicitors and leaflettors to achieve minimally acceptable passenger traffic flow. FAA

knows of no better or less restrictive way to limit the number of leaflettors and solicitors than by issuing permits. Additionally, the regulation was not intended for the comfort an convenience of travelers, but rather, it was needed to protect travelers against unacceptable obstruction and congestion.

Several significant concerns were raised about the process of applying for a permit. First, it was vigorously asserted that those who are distributing literature have a right to anonymity that would be violated by the application process. Indeed, the Supreme Court has recognized that right to anonymity in *Talley* v. *California*, 362 U.S. 60 (1960). The Court stated

> "[I]dentification and fees of reprisal might deter perfectly peaceful discussions of public matters of importance particularly where door to door solicitation seeks discussions of sensitive and controversial ideas 367 U.S. at 625.

FAA believes that where no money is sought from the public, interests are served by merely requiring a permit so that the number of distributors and places of distribution may be regulated. There is, however, no compelling need for the leaflettor to identify himself/herself. The permit will be marked as one for distribution, not sale, of non-commercial printed matter.

One commenter expressed concern that some applicants might freeze out other applicants for an entire week by applying for a permit to exclude others. Because the FAA was concerned about the burden on applicants to apply for a daily permit, the NPRM proposed the permit last for seven days. To prevent undue monopoly of the permits, the FAA accordingly changes the duration of the permit to two days. Because of the shorter duration, assuring a greater turnover rate, there will be protection against monopolizing permits. Furthermore, the twenty four hour waiting period to reapply is deleted, as it is no longer needed because of the greater turnover rate.

One commenter expressed disagreement with the "first come, first serve" procedure for issuing permits. The commenter stated that this procedure is too competitive. The FAA believes the "first come, first serve" rule is the fairest approach in issuing a permit. This procedure excludes any discretion on the part of FAA to pick and chose which groups or individuals will be issued a permit first.

In one important respect several commentors misunderstood the powers and remedies available to the FAA under the regulation to deny or revoke permits. A permit will be issued upon completion of the application form. In deference to the rights protected by the constitution, there is no provision in the regulation for denial of a permit on the basis of suspected, false statements in the application. Nor is there any provision for revocation of a permit already issued, for any reason. For example, § 159.94(b), which makes it illegal to solicit under a permit issued in response to an intentionally false application, has no effect on the permit issuance process other than deterrence of false representations. In the event of a suspected violation of this provision, or of any other provision of § 159.94, the actions available to the FAA are, first, the prosecution of the individual for violation of airport regulations, violation of which is a misdemeanor or second, the seeking of a District Court injunction against further solicitations by the individual at the airports. Either alternative requires judicial review of the case initiated by the FAA, clearly assuring due process to the individual concerned.

Solicitors

Two commentors contend that FAA should not even require a solicitor who solicits on behalf of an organization to provide documentation to that effect. They believe that it would be less restrictive for the person simply to state the name of the group he or she claims to represent. We do not agree. FAA believes that organizations sending a representative to solicit on their behalf will willingly, and can reasonably be required to, document this representation with a simple letter. Such a minimal requirement is hardly burdensome. It would seem to be more, not less objectionable if FAA were to "investigate" and make its own determination of whether an individual represents an organization as claimed. FAA does not believe it is appropriate that it engage in this type of extended investigative activity.

The proposed regulation requires the name of the applicant's supervisor responsible for the applicant's activity at the airports. This is attacked as vague. FAA disagrees. The requirement simply and clearly calls for the name of someone in charge of the solicitor at the airport. However, in recognition that in some instances there may not be a supervisor, the regulation as proposed is amended to specify "if applicable". An applicant for a permit will not be denied a permit on the basis of the failure to provide this name.

Charitable Causes

Several commenters called attention to the recent Supreme Court decision in *Village of Schaumberg* v. *Citizens for a Better Environment*, 48 LW 4162 (Feb. 20, 1980), in which the Supreme Court clearly recognizes that charitable solicitation is so closely intertwined with speech interests that it is within the protection of the First Amendment. This settles a question which FAA viewed as heretofore open. The statement in the preamble of the NPRM that "the solicitation of funds by individuals not associated with the free exercise of religion is not constitutionally protected" is no longer correct.

Given that charitable solicitation is afforded at least some degree of constitutional protection, FAA is presented with the question of how it may inquire into the legitimacy or non-commerciality, of an espoused charity, and whether it may require documentation that the organization is a charity before the individual is allowed to solicit funds on the airport.

In *Schaumberg*, the Supreme Court struck down a prohibition against soliciting for a charitable organization if more than 25% of the receipts of that organization are used on fund raising salaries and overhead. The Court found this standard unconstitutionally overbroad, in that it grouped legitimate charitable organizations engaged primarily in research, advocacy, or public education with those that are in fact using the charitable label as a cloak for profitmaking. The Court, however, did not foreclose any inquiry into whether an organization is a charity, and indeed noted the failure of the Village to employ more precise measures to separate one group from the other. The Court further implied that an organization's eligibility for tax exempt status under federal law could be determinative of its eligibility for preferred constitutional status in its fund raising efforts. Attainment of such tax exempt status is at least verifiable. This verification is what FAA sought to obtain in proposed 159.93(e)(E)(iii) which required a copy of an official Internal Revenue Service ruling or letter stating that the applicant's organization or its parent organization qualifies for tax exempt status under 26 U.S.C. 501(c)(3), (c)(4) or (c)(5).

FAA believes that if there is a reasonable means of verifying the representations made by a solicitor those means should be used. Two commenters state that while a tax exempt status might be useful in determining who is a charitable group, this is a different question from whether applicants should be required to provide evidence of that status to airport officials. In view of this concern that the

documentation is burdensome on the applicant, FAA has reconsidered the requirement. In lieu of documentation FAA will require only that the applicant state if his or her organization has received an IRS determination for exempt status under Section 501(c)(3), (c)(4), or (c)(5), or has an application for such status pending. No further evidence will be required. FAA may, if it chooses, make further inquiry with IRS as to the currency or accuracy of the applicant's statement.

FAA is also revising the final regulation to take into account recent legislation on the registration of charitable organizations in the State of Virginia, in which both airports are located. The State of Virginia requires that every charitable organization, except as exempted, which intends to solicit contributions within the Commonwealth, or have funds solicited on its behalf, shall, prior to any solicitation, file a registration statement with the Administrator of Consumer Affairs, VA. Code 57–49. Evidence that an organization is currently registered as a charity in Virginia will suffice as a means of verifying to FAA that the organization is a charity, for purposes of solicitation at the airports. Applicants may use either the Virginia registration or the IRS tax-exempt status at their choosing.

Political Organizations

Two commenters believe that the definition of a political organization in 159.93(c)(2)(E)(ii) is too restrictive, and would not include groups that advocate positions on matters of public concern but work for political causes unrelated to elections or legislation. FAA does not intend to be restrictive in this definition. Advocacy groups such as those protected by the *Village of Schaumberg* have been added to the definition in the final rule.

Traffic Flow Study

Several comments were critical of the traffic flow study done for the FAA by a planning consultant firm. Two commenters attacked as unconstitutional an assumption that solicitation would not be allowed in the public waiting areas or seating lounges based on a captive audience theory. FAA believes that the assumption is reasonable. Persons in the lounges of course can get up and move away to avoid a solicitor. However, FAA does not believe that there is any justification for disrupting the seating lounge by creating a situation where the air traveler has to move away from unwanted solicitation. The solicitors have access to these persons as they enter or leave the seating lounges.

Furthermore, these seating areas are not areas where pedestrian traffic flows and therefore they are properly excluded from any calculation of the impact of non-commercial activity on such flow. Thus, even if solicitation were permitted in the seating area, that area would not have been added into the calculation of the total number of solicitors. That number was based on *a level of service* in the traffic flow area. Level of service is another way of describing the traffic flow in the terminal. The study applied the standard level of service descriptions used for planning public facilities, transportation facilities, shopping malls, etc. The levels of service were not arbitrarily applied to the airports as one commenter asserted. At both airports the level of service is restricted. For example, at National Airport, the study notes, the freedom to select individual walking speed and freely pass other pedestrians is restricted. Where pedestrian cross movements and reverse flows exist, there is a high probability of conflict requiring frequent adjustment. At Dulles Airport during the peak hours of the afternoon the majority of persons would have their normal walking speeds restricted and reduced due to difficulties in bypassing slower moving pedestrians and avoiding conflicts.

Analysis was then performed to determine if the addition of a number of solicitors or leaflettors would further reduce these existing levels. FAA will permit the highest number of solicitors that would not result in a reduction in the present service level. The FAA does not believe that either of the present service levels at National or Dulles should be lowered to the next lowest level by increasing the number of solicitors beyond the number in the Final Rule. Such an action would not be consistent with the proper exercise of the FAA's statutory responsibilities at the Airport.

Prohibitions and Penalties

Several commenters expressed concern that the prohibition against behavior which "embarrasses" or "ridicules" airport patrons is vague and overly broad. The FAA agrees, and therefore, has omitted the words "embarrass" and "ridicule" from the NPRM section on prohibited acts. (159.94,f)

The proposed penalty provision, § 159.191(c), which provided that any person wilfully violating the solicitation regulation shall be prohibited from engaging in non-commercial activity at the airport for not more than six months, was criticized as being an unlawful prior restraint on protected First Amendment rights. This amendment merely intended to notify violators that such restriction may be imposed. It was not intended to arrogate this authority to the FAA or airport management. Violators of any airport regulations are guilty of a misdemeanor which is punishable by up to six months in prison. In lieu of a jail sentence, the courts already possess the authority to require a convicted person to not conduct such activity on the airports. The penalty, like others, can only be imposed by a court of law after due process to the accused. Because FAA recognizes that the court already has this authority, the final rule has been modified by deleting § 159.191(c).

Comments Supporting Broader Regulation of Solicitors and Leaflettors

One commenting airline company supported the proposed rule, but contended that the main terminal concourse was not large enough to accomodate even two solicitors or leaflettors as proposed. The terminal traffic study used by FAA in development of the regulation also indicated that any solicitors in the main terminal would cause unacceptable interference with traffic flow. However, FAA will continue to allow two solicitors in this area in the interest of accomodating First Amendment activities to the maximum extent consistent with the terminal's function. The FAA will monitor this activity and should it present an unacceptable obstacle to traffic patterns, FAA is prepared to modify the regulation.

Another commenting airline company recommended that only one solicitor be permitted in each terminal complex. FAA has, however, followed the recommendations of its passenger study on this point, and permitted more solicitors where indicated. The commenter further recommended that soliciting organizations be required to lease space, as a business would be required to do, and to publish income and expenditure statements. While FAA can appreciate the concern of airport businesses that solicitors can use the airports without cost for fund-raising purposes, FAA recognizes that it is the solicitor's right to do so. On the second point, any benefits which would be realized by a financial disclosure requirement are already obtained, to the extent necessary, by reference to the IRS determination and Virginia Consumer Affairs registration. Therefore no such disclosure requirement has been included in the final rule.

The Air Transport Association of America (ATA), of which 16 incumbent

carriers at the airports are members, generally supported the proposed regulations as directly related to the promotion of safety and the reduction of burdens for air travelers. ATA recommended several amendments to the proposed rule including, first, an increase in the minimum distance specified in Section 159.94(d) from 10 feet to 15 feet. However, maintaining a 10 foot distance from the critical points on the airport and persons in line at these points is sufficient to prevent the interference with the operation of these areas. The 10 foot distance is also not unduly restrictive on the solicitors and is retained in the final rule. ATA also recommended that applicants for leafletting permits be required to provide the same information as for solicitation permits. For reasons discussed above, however, FAA has deleted all information requirements for leaflettors.

ATA further requested that § 159.94(d)(6) be amended to add "or other building tenants" to the prohibition on solicitation within 10 feet of "Premises leased for the exclusive use of a concessionaire". FAA is sensitive to the possible interference with normal airport business caused by solicitation. However, other restrictions set forth in the same section would appear to address this concern adequately, particularly the limitations on solicitation near ticket counters, baggage claims areas, departure gate check-in counters and lounges, and doorways. ATA expressed a related concern which FAA believes legitimate: the possibility that the regulations, which delineate rights to as well as limitations on solicitations, might be construed to affect the rights of existing airport lessees. FAA has therefore included in the final rule a provision which preserves the present rights of such lessees in areas under their exclusive control.

Two final ATA recommendations were not incorporated in the final rule. First, ATA proposed that permits for Dulles be limited continuously as at National, rather than at specific hours. FAA believes the lack of congestion at Dulles during off-peak hours precludes the necessity for limiting the number of solicitors at all times. Second, ATA recommends that FAA retain the authority to impose a total ban on solicitation during heavy traffic or emergency periods, such as Thanksgiving and Christmas holidays, or heavy snow condition. FAA does not believe that this action is necessary in light of the general constitutional protection of peak-hour solicitation, when access to the public is most effective. In genuine emergency situations FAA is confident that its existing police powers are sufficient to take all actions reasonably necessary.

The Final Rule

The Federal Aviation Administration hereby amends Subpart D, "Rules of Conduct," of Part 159 of the Federal Aviation Regulations (14 CFR Part 159) as follows:

1. By amending § 159.91, "Business and Commercial Activity," by deleting the heading and the entire section consisting of paragraphs (a), (b) and (c) and substituting for them the following:

§ 159.91 Commercial activity.

(a) No person may engage in any commercial activity on the Airport without the approval of, and under terms and conditions prescribed by, the Airport Manager.

(b) For the purpose of this section "commercial activity" means any activity undertaken for profit including the sale, provision, advertisement or display of goods or services."

2. By adding a new § 159.93 to read as follows:

§ 159.93 Certain non-commercial activities.

(a) This section applies to the following activities undertaken not for profit but for non-commercial purpose (hereinafter referred to as "non-commercial" activities):

(1) The distribution of any written or printed matter to the general public including distribution for the conduct of surveys and petitions. The distribution of items or material other than printed material will be treated as a "commercial activity" under this Part.

(2) The solicitation of funds from the general public whether or not in connection with the distribution of written or printed matter.

(3) The sale of written or printed matter by persons who have identified themselves as religious solicitors pursuant to paragraph (c)(2)(e)(i) of this section. All other sales of any material, items, or services will be treated as a "commercial activity" under this Part.

(b) Each person conducting any non-commercial activity must hold a valid permit issued by the Airport Manager and conduct the activity in conformity with applicable laws, regulations and the terms of the permit. Each permit shall describe the activity authorized and the area in which it may be conducted.

(c) *Procedure:* Unless by prior application all available permits have been granted, applications will be processed as follows:

(1) Each person who seeks to distribute written or printed matter without soliciting funds shall immediately be given a single permit for leafletting for non-commercial purposes upon his request.

(2) Each person who seeks to solicit contributions or sell or distribute printed matter, either in connection with religious expression or as representative of a non-commercial organization, shall immediately be given a single permit upon his submission of an application, signed by the applicant, containing the following:

(i) The applicant's name, address and telephone number;

(ii) If the applicant purports to represent an organization, the name, address and telephone number of the organization, and a letter or other documentation that the applicant has authority to represent that organization.

(iii) The name and title of the person in the organization who will have supervision of and responsibility for the activity at the airport, if applicable;

(iv) A statement that the sale of printed matter and/or the solicitation of funds is for non-commercial purposes; and

(v) One of the following:

(A) A Statement signed by the applicant that the applicant represents and will be soliciting funds for the sole benefit of a religion or religious group;

(B) A statement signed by the applicant that the applicant represents and will be soliciting funds for the sole benefit of a political organization the primary function of which is to influence the nomination, election, or appointment of one or more individuals to Federal, state or local public office; to influence Federal, state or local legislation; or to advocate issues or causes to the public.

(C) A statement signed by the applicant that the applicant's organization has received an official Internal Revenue Service (IRS) ruling or letter of determination stating that the organization or its parent organization qualifies for tax-exempt status under 26 U.S.C. Section 501(c)(3), (c)(4), or (c)(5).

(D) A statement signed by the applicant that the applicant's organization has applied to the IRS for a determination of tax-exempt status under 26 U.S.C. 501(c)(3), (c)(4), or (c)(5), and that the IRS has not yet issued a final administrative ruling or determination on such status; or

(E) A statement signed by the applicant that the applicant's organization has on file with the Virginia Administrator of Consumer Affairs a current registration statement

in accordance with the Virginia Annotated Code, Section 57–49 (1978 Cumulative Supplement), "Registration of Charitable Organizations".

(d) Failure to submit the information required by subsection (c) shall result in denial of a solicitation permit. Upon request, for a leafletting permit, or upon submission of a completed signed application, for a solicitation permit, a permit shall be issued unless all available permits have been issued to prior applicants.

(e) Applications for permits must be submitted to the Operations Office of the airport concerned. Permits will be granted on a "first come, first served" basis. The area will be granted on a "first come, first choice" basis. The permits are not transferable except among individuals who have completed and submitted applications for the same permit.

(f) *Duration.* Each permit shall authorize the holder to conduct non-commercial activities for a period of 48 hours. Permits shall not be extended or renewed. After the expiration of the permit a new leafletting or solicitation permit may be issued to the former permit holder upon request or submission of a new application respectively. In such a case, applicants may be permitted to incorporate by reference any required documentation filed with a previous application.

(g) *Areas.* Each permit shall specify the area in which the non-commercial activity may be conducted by the permit holder. Permits shall be issued for the following areas up to the maximum number indicated:

(1) Washington National Airport:

(i) The Northwest/Trans World Airlines lobby (2),

(ii) The American Airlines lobby (1),

(iii) The main concourse and balcony (2),

(iv) The north terminal (2),

(v) The sidewalk in front of the Piedmont Aviation Terminal (1).

(2) Dulles International Airport between 4 p.m. and 8 p.m.

(i) upper level main concourse south of ticketing area (4),

(ii) lower level south concourse (1),

(iii) lower level east (1),

(iv) lower level west (1).

The areas are on display on a floor plan at the Operations Office of each Airport.

(h) Nothing in this Part shall be construed as impairing or expanding any right which an airport lessee may otherwise have, by virtue of its leasehold interest in airport premises, to regulate access to those areas under its exclusive control.

3. By adding new § 159.94 to read as follows:

§ 159.94 Prohibited conduct relating to non-commercial Activity.

No person may conduct non-commercial activity:

(a) Without a permit or with a permit that has expired.

(b) With a permit issued in response to an intentionally false application.

(c) With a permit outside the area designated on the permit.

(d) Within 10 feet of the following: (1) A ticket counter, (2) A baggage claim facility, (3) A departure gate check-in counter, (4) A departure gate lounge, (5) An anti-hijack security screening point, (6) Premises leased for the exclusive use of a concessionaire, (7) Restroom facilities, (8) A stair, escalator or elevator, (9) A doorway or entrance way, (10) A motor vehicle with embarking or disembarking passengers, (11) A public service information counter, (12) Persons waiting in line at any of the above listed areas.

(e) If that person is selling written or printed matter or soliciting funds, without wearing or displaying, in a conspicuous manner, the name of the organization that the person represents.

(f) By use of threatening gestures, or by language directed at another person in a manner intended to harass that other person.

(g) By intentionally touching or making physical contact with another person unless that other person has consented to such physical contact.

(h) By repeatedly attempting to distribute written or printed matter to, or to solicit funds from, another person when that other person has indicated to the solicitor that he or she does not wish to accept any matter or to make a donation.

(i) By use of a loudspeaker, sound or voice amplifying apparatus without the permission of the Airport Manager.

(j) By setting up a table, counter or stand without the permission of the Airport Manager.

(Secs. 2 and 4 of the Act for the Administration of Washington National Airport, 54 Stat. 686 as amended by 61 Stat. 94; Secs. 4 and 10 of the Second Washington Airport Act, 64 Stat. 770; sec. 313 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1359); sec. 6, Department of Transportation Act (29 U.S.C. 1655); Sec. 501 of Pub. L. 96–193, February 18, 1980)

Note.—The FAA has determined that this document involves a regulation which is not significant under Executive Order 12044, as implemented by DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). The economic impact of the proposal is judged to be minimal and a detailed evaluation is not required.

Issued in Washington, D.C., on May 20, 1980.

Quentin S. Taylor,

Deputy Administrator.

[FR Doc. 80-15668 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-13-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1241

Contract Appeals; Correction

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule with comments requested; correction.

SUMMARY: In 45 FR 23406–23413, April 7, 1980, NASA amended the rules of procedure for the adjudication of contract appeals before the NASA Board of Contract Appeals by adding a new subpart 1241.2 to implement the practices and procedures required by the Contracts Dispute Act of 1978, Pub. L. 95–563, effective March 1, 1979. This amendment makes editorial changes to renumber the following sections: § 1241.20 to § 1241.196; § 1241.21 to § 1241.197; § 1241.22 to § 1241.198; § 1241.23 to § 1241.199; and § 1241.24 to § 1241.200.

DATE: April 7, 1980.

ADDRESS: Frederick J. Lees, Chairperson, Board of Contract Appeals, Code NC–9, NASA Headquarters, Washington, D.C. 20546.

FOR FURTHER INFORMATION CONTACT: Frederick J. Lees, 202–755–3481.

In the final rule (FR Doc. 80–10298) published on April 7, 1980 (45 FR 23406) the following corrections should be made:

PART 1241—[AMENDED]

1. On page 23407, the section headings in the second and third columns should be renumbered as follows: § 1241.20 to § 1241.196; § 1241.21 to § 1241.197; § 1241.22 to § 1241.198; § 1241.23 to § 1241.199; and § 1241.24 to § 1241.200.

2. The table of contents on page 23407, the first column, should be corrected accordingly.

Margaret M. Herring,

Federal Register Liaison Officer.

May 20, 1980.

[FR Doc. 80-16032 Filed 5-23-80; 8:45 am]

BILLING CODE 7510-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 274

[Docket No. RM79-3]

Determinations by Jurisdictional Agencies; Colorado Application for Alternative Filing Requirements

Issued: May 20, 1980.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final Rule.

SUMMARY: This rule adds § 274.208(a) to the Federal Energy Regulatory Commission Regulations implementing the Natural Gas Policy Act of 1978. The new section provides alternative filing requirements for certain well determination applications to the Colorado Department of Natural Resources' Oil and Gas Conservation Commission.

EFFECTIVE DATE: May 20, 1980.

FOR FURTHER INFORMATION CONTACT: Victor Zabel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 357-8559.

SUPPLEMENTARY INFORMATION: On January 14, 1980, the Colorado Department of Natural Resources, Oil and Gas Conservation Commission (Colorado) filed an application with the Commission for approval of alternative filing requirements pursuant to § 274.207 of the Commission's regulations. The proposed alternative filing requirements would enable operators to apply for eligibility determinations under section 103 of the Natural Gas Policy Act of 1978 (NGPA) for additional wells in existing proration units in the Sussex and Shannon reservoir in the Spindle Field, and in the Sessex reservoir in the Hambert Field, in Adams and Weld Counties, Colorado, without repeated submissions of geological and engineering data to show that the additional well is necessary to effectively and efficiently drain a portion of the reservoir covered by a proration unit that cannot be effectively and efficiently drained by any existing well within the proration unit.

Section 103 of the NGPA establishes the maximum lawful price for natural gas produced from new, onshore production wells. Under § 271.305(b) of the Commission's regulations, an additional well drilled on or after February 19, 1977, in an existing proration unit may qualify for the section 103 price if the jurisdictional agency finds that the well is necessary to effectively and efficiently drain a portion of the reservoir covered by the proration unit.

An applicant seeking a determination of eligibility under § 271.305(b) to collect the section 103 price is required to file with the appropriate jurisdictional agency the information specified in § 274.204 of the Commission's regulations. Under § 274.204(f), an applicant must submit, on a well-by-well basis, geological evidence and engineering data showing that an additional well within the existing proration unit is necessary to effectively and efficiently drain a portion of the reservoir covered by the proration unit, which cannot be effectively and efficiently drained by any existing well in the proration unit.

Under § 274.207, however, a jurisdictional agency is authorized to apply for Commission approval of alternative filing requirements. Colorado's application for approval of alternative filing requirements is based on those portions of Colorado's Order Nos. 304-5, 250-12, 250-14, 250-16, 250-17, 250-19, 250-20, 250-21, and 250-23 that authorize the drilling of additional wells into existing proration units in the Shannon and Sussex reservoirs in the Spindle Field, and in the Sussex reservoir in the Hambert Field, in Adams and Weld Counties, Colorado. In lieu of the filing requirements presently found in § 274.204(f), Colorado would simply require that the applicant file a statement specifying that the applicant is seeking a determination with respect to an additional well drilled into an existing proration unit and specifying the applicable order (from the orders mentioned above) which permitted the drilling of the additional well.

Colorado has concluded that the proposed alternative filing requirements provide substantial evidence on which to base a determination, since the pertinent geological and engineering data showing the necessity for second wells in existing proration units has already been accumulated during hearings under oath, based upon which the relevant orders were adopted. Colorado has furnished the pertinent geological and engineering data and other material which were offered into the record at the hearings concerning the above-mentioned orders in its application for approval of alternative filing requirements. Colorado asserts that this evidence is sufficient for all determinations involving wells drilled under the authority of these orders.

The Commission has review the geological and engineering data submitted by Colorado. The Commission finds that the proposed alternative filing requirements will provide sufficient information and substantial evidence upon which determinations under section 103 can be based. Accordingly, the Commission is amending Part 274, Subpart B, in § 274.208 to adopt the alternative filing requirements proposed by Colorado for applications for new, onshore production well determinations for second wells drilled into existing proration units pursuant to the above-mentioned orders.

The Commission's regulations in § 271.305(c) require jurisdictional agencies to notify the Commission when findings are made under § 271.305 that an additional well in an existing proration unit is necessary for effective and efficient drainage. Since Colorado's orders, listed above, find that infill drilling of additional wells in established proration units is necessary on a field-wide basis for the effective and efficient drainage of portions of the reservoirs covered by proration units which cannot be effectively and efficiently drained by an existing well within those units, the Commission finds that there is no need for Colorado to notify the Commission on an individual well basis that it has made the effective and efficient drainage finding for and individual well. Accordingly, for second wells drilled into existing proration units pursuant to the orders listed above, the Commission deems satisfied the requirements of § 271.305(b) and (c) with respect to determinations made by Colorado.

Further, § 274.204(d)(4) requires the filing of an oath statement that the applicant's conclusion that the natural gas for which he seeks a determination is produced from a new, onshore production well is based on documents submitted in the application. The oath statement must be modified for wells covered by the alternative filing requirements inasmuch as the applications will not contain all the documents relied on by the applicant in making the conclusion. Therefore, the phrase "documents submitted in the application" will be deleted from the oath statement, as applicable to persons seeking section 103 eligibility determinations for second wells drilled into existing proration units pursuant to the subject orders.

Public Procedures and Effective Date

A notice regarding Colorado's application was issued on February 21, 1980. (45 FR 13519, February 29, 1980). The comment period expired on March 7, 1980. No comments were received.

In view of the above discussion, the Commission approves the alternative

filing requirements submitted by Colorado and deems satisfied the provisions of § 271.305 (b) and (c) and § 274.204(d)(4) as noted above. The Commission believes that good cause exists to make the alternative filing requirements effective immediately for all determinations which have not yet become final under § 275.202 as of the day before the date of issuance of this order.

(Natural Gas Act, as amended, 15 U.S.C. § 717–717w; Department of Energy Organization Act, 42 U.S.C. § 7107–7352 Exec. Order No. 12009, 42 FR 46267; Natural Gas Policy Act of 1978, 15 U.S.C. § 3301–3432)

In consideration of the foregoing, Part 274 of Subchapter H, Chapter I, Title 18 Code of Federal Regulations is amended as set forth below, effective immediately for all determinations which have not yet become final under § 275.202 as of the day before the date of issuance of this order.

By the Commission.

Kenneth F. Plumb,

Secretary.

PART 274—DETERMINATIONS BY JURISDICTIONAL AGENCIES

Section 274.208 of Part 274 is amended by inserting a new paragraph (c) to read as follows:

§ 274.208. Alternative filing and notice requirements accepted by the Commission.

* * * * *

(c) *Certain Infill Wells in the Sussex and Shannon reservoirs in the Spindle field and in the Sussex reservoir in the Hambert Field in Adams and Weld Counties, Colorado.*

(1) A person seeking a determination for purposes of Subpart C of Part 271 that a second well drilled in accordance with the Colorado Department of Natural Resources' Oil and Gas Conservation Commission's Order Nos. 304–5, 250–12, 250–14, 250–16, 250–17, 250–19, 250–20, 250–21, and 250–23 in the Sussex and Shannon reservoirs in the Spindle field and in the Sussex reservoir in the Hambert Field in Adams and Weld Counties, Colorado is a new, onshore production well, shall file with the Colorado jurisdictional agency an application which contains, in lieu of the information specified in § 274.204, the following items:

(i) FERC Form No. 121;

(ii) The well completion report;

(iii) A location plat which locates and identifies the State law proration unit (as defined in § 271.305(a)(2)) and the well for which a determination is sought and all other wells within the State Law proration unit in which the well for which a determination is sought is located;

(iv) A statement by the applicant, under oath:

(A) That the surface drilling of the well for which he seeks a determination was begun on or after February 19, 1977;

(B) That the well satisfies any applicable Federal or State well spacing requirements;

(C) That the applicant has concluded that to the best of his information, knowledge and belief, the natural gas for which he seeks a determination is produced from a new, onshore production well; and

(D) That the applicant has no knowledge of any other information not described in the application which is inconsistent with his conclusion;

(v) If the jurisdictional agency so requires, certified copies of records relied on by the applicant including copies of the agency's official files; and

(vi) A statement referencing Colorado's Oil and Gas Conservation Commission's Order Nos. 304–5, 250–12, 250–14, 250–16, 250–17, 250–19, 250–21, or 250–23, as appropriate.

(2) With respect to wells to which this paragraph applies, receipt by the Commission of a notice of determination pursuant to § 274.104 shall be deemed to satisfy:

(i) The requirement of notice to the Commission under § 271.305(c); and

(ii) The requirement of § 271.305(b)(1) that appropriate geological and engineering data be included in the notice of determination.

[FR Doc. 80-15892 Filed 5-23-80; 8:45 am]

BILLING CODE 6450-85-M

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 40

Farm Labor Contractor Registration; Documents Acceptable as Evidence of a Bona Fide Inquiry of Employability Status

AGENCY: Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: This rule expands the current list of documents which will be accepted by the Department of Labor as constituting proof that a farm labor contractor has made a *bona fide* inquiry into the status as a United States citizen or as a person lawfully authorized to work in the United States of each prospective employee. This will permit farm labor contractors to accept additional types of material as evidence that a person is a citizen of the United States or is a person lawfully authorized to work in the United States.

EFFECTIVE DATE: May 27, 1980.

FOR FURTHER INFORMATION CONTACT: Solomon Sugarman, Chief, Branch of Farm Labor Law Enforcement, Office of Child and Farm Labor, Wage and Hour Division, Room S-3504, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, Telephone 202–523–7531.

SUPPLEMENTARY INFORMATION:

Background

The Farm Labor Contractor Registration Act of 1963, as amended (7 U.S.C. 2041(a), *et seq.*), provides sanctions against any farm labor contractor who knowingly engages in recruiting, employing, or utilizing the services of any person who is an alien not lawfully admitted for permanent residence nor authorized by the Attorney General to accept employment. Under the provisions of 29 CFR 40.51(p) (which became effective in 1976) a contractor must show that he or she has made a *bona fide* inquiry into the status of each prospective employee. The same section lists certain documents upon which reliance will be accepted by the Department of Labor as constituting such a *bona fide* inquiry. It has been our experience that the limited nature of the present list has resulted in the denial of employment to United States citizens and legally admitted aliens who do not have a birth certificate or other listed document.

On March 4, 1980, a document was published in the Federal Register (45 FR 14070) proposing to amend 29 CFR 40.51(p) by adding certain additional documents to the list of those which will be accepted as evidence of a *bona fide* inquiry by a farm labor contractor into the employability status of a prospective employee.

The Department, in its administration of the Act and of the regulations, 29 CFR Part 40, had found those documents, in the absence of evidence to the contrary, to constitute a *bona fide* inquiry into the status of a prospective worker under Sections 5(b)(6) and 6(f) of the Farm Labor Contractor Registration Act of 1963, as amended (7 U.S.C. 2044(b)(6) and 2045(f)).

Changes Made to Proposed Rule

As a result of comments received, the following changes in the proposed rule are made:

1. United States Armed Forces Discharge Papers will be included in the list.

2. The words "employment in agriculture" in § 40.51(p)(4) are changed to "such employment" inasmuch as the INS grants employment authorization without restricting the type of employment allowed, and the Department of Labor does not wish to deprive alien workers of employment in agriculture merely because agriculture is not specified.

3. Several commenters remarked upon the "looseness" of the proposed self-declaration of citizenship. These commenters have overlooked the fact that the "Self-declaration" contains additional safeguards. It must be executed in the presence of an appropriate official of the United States Employment Service or any of its affiliated offices and any false statement is punishable by a fine or imprisonment, or both. The self-declaration must also list the names of three adult citizens who can verify on request the representations made by the declarant. In order to further tighten the procedure surrounding the declaration, the rule has been changed to require that the signature of the Employment Service official be affixed in the presence of the applicant.

4. In response to a comment, the proposal has been modified to permit the Department of Labor, Bureau of Employment Security, Commonwealth of Puerto Rico, to attest by the issuance of a certificate, based upon the examination of any of the documents prescribed by § 40.51(p)(1)(i) through (xi), that the individual named and identified by picture on the certificate was born within the United States or territory or possession thereof at the place and on the date specified thereon and which sets forth such individual's home address and social security number. The use of this certificate is based upon the Secretary's determination that it satisfies the essential requirements of Section 5(b)(6) of the Act. The Secretary has also determined that any other State (as that term is defined in Section 3(f) of the Act) which adopts a similar certificate may apply for similar status.

5. It was suggested that the Social Security number be omitted from the declaration in § 40.51(p)(1)(xi) inasmuch as it does not help in determining citizenship.

Although not a means of identification, the Social Security number provides a simple method for systematizing the records of these documents. A change has been made, however, to make it clear that the inclusion of the Social Security number is voluntary.

Recommendations Not Adopted

Certain other recommendations have been carefully considered but not adopted. The following suggestions were not adopted for the reasons stated:

1. *Comment:* It was suggested that detasseling crews be exempted from the *"bona fide* inquiry" requirement.

Response: In 1978, Congress amended the Farm Labor Contractor Registration Act by adding Section 3(b)(10), exempting a contractor whose only farm labor contracting activity involves supplying persons (whose principal occupation is not farmwork) for detasseling, roguing, and other incidental farmwork for not more than four weeks in any calendar year, provided those workers are not required by the work to be away from their homes overnight and provided further that no persons under eighteen years of age are engaged by the contractor to provide transportation. A contractor who meets all the requirements of that exemption is not subject to any provision of the Act. Specifically, such a contractor would not be subject to the *"bona fide* inquiry" requirement. There are, however, contractors who do not satisfy the requirements of that exemption, and it would be inappropriate to exempt them by administrative action from the *"bona fide* inquiry" provision of 29 CFR 40.51(p).

2. *Comment:* It was suggested that items (vii), baptismal certificate; (viii), other religious record; (ix), tribal enrollment card; and (xi), self-declaration of citizenship, be stricken, as they are highly susceptible to forgery.

Response: While such documents may be forged, few documents cannot be. However, the Department will deem good-faith reliance on them, even if in error, to constitute a *bona fide* inquiry into crew members' employability. Of course, a farm labor contractor who knows or who has reason to believe that a document is false or forged would not be deemed to have relied in good faith upon such a document.

3. *Comment:* It was suggested by several commentators that item (xi), the self-declaration of citizenship, be stricken.

Response: The primary objection raised was that the Employment Services lack the expertise to determine an individual's citizenship status. This rule does not require that an Employment Service representative attest to the accuracy of the declaration but only to the signature thereon. However, as previously indicated, the so-called "self-declaration" contains additional safeguards. These safeguards include the requirements that the declaration must be executed in the presence of an appropriate official of the U.S. Employment Service or any of its affiliated offices and any false statement is punishable by a fine or imprisonment, or both. The self-declaration must also list the names of three adult citizens who can verify on request the representations made by the declarant. The purpose of this amendment is to preclude a citizen who has no other documentation from being denied employment.

4. 3Comment: The recommendation that an agreement be sought among the nations of North America and the Caribbean under which migrant workers might move freely among those nations was not adopted.

Response: This rule is not an appropriate place to pursue such an agreement; the suggested change is one involving the immigration policies of the United States and not within the scope of the Secretary's responsibility.

5. *Comment:* Numerous other documents were suggested as acceptable evidence of citizenship or employability; none were adopted.

Response: These documents are:

a. Hospital or physician's office record of birth. It was felt these documents would be too difficult to verify.

b. Federal census record. The Federal census record does not establish citizenship or resident alien status.

c. School record. This, too, would generally not establish an individual's citizenship or resident alien status.

d. Social security card or application. These documents have no relationship—positive of negative—to employability.

e. Selective Service System registration card. Since there are currently no registration requirements it is not reasonable to specify such a document.

f. Family Bible record. The Department of Labor does not consider this to be the type of consistently reliable record necessary for this purpose.

g. Voter Registration card. This document may in some States be obtained upon application made by mail without establishing citizenship.

6. *Comment:* It was suggested that the Department abandon the creation of "a new bureaucracy to administer the new declaration of citizenship form," "adding to the burden of an already existing bureaucracy," or "narrow administrative empire-building."

Response: The self-declaration of citizenship will be, simply, a statement made by a farm worker in writing, witnessed (not investigated nor attested by a representative of the United States

Employment Service (USES) system, and filed with a local office of the USES system. Good-faith reliance upon such a declaration—or upon any other document listed in § 40.51(p)—will protect a farm labor contractor from charges of violating Sections 5(b)(6) and 6(f) of the Farm Labor Contractor Registration Act even if the worker should be, in fact, an unemployable alien. There will be no additional staff to administer this declaration.

7. *Comment:* Suggestions were made to change the requirements of the self-declaration of citizenship, as follows:

a. Strike the requirement that the names and addresses of three adult citizens of the United States be included.

Response: These names and addresses provide a means of confirming the statement's accuracy and represent an additional safeguard against falsification.

b. Add wording to specify that the form does not satisfy INS requirements nor those of many States which have statutory provisions prohibiting the employment of illegal aliens.

Response: The Department believes this is unnecessary inasmuch as the declaration is not for INS or State purposes and need not be on any particular form, so long as it includes all the required information.

8. *Comment:* It has been suggested that the self-declaration of citizenship be reduced to wallet size and that this reduction include a photograph.

Response: While this suggestion has merit, to implement it would be prohibitively costly, and it is therefore not adopted by the Department. Of course, the holder of the declaration is free to have the declaration reduced to wallet size if desired.

9. *Comment:* Recommendations concerning the approach to be taken by Employment Service representatives toward the self-declaration ranged from taking the initiative when it is found that a worker has no other documentation to acting only when a request for self-declaration is made as a result of specific job openings announced through the Employment Service system.

Response: The Department feels that it is not appropriate in this rule to set detailed guidelines for Employment Service (ES) personnel in dealing with this matter. In general, all Employment Service offices are expected to accept all such declarations from registered job applicants and retain them in their filing systems.

10. *Comment:* Finally, it was urged that the Department of Labor and the Immigration and Naturalization Service join in preparing a single document acceptable to both for determining employability.

Response: This recommendation was not adopted since the INS requires different and more comprehensive information pursuant to a different statute having a different purpose.

Effective Date

This rule relaxes an existing restriction and allows additional documentation to be accepted by a farm labor contractor as evidence that a prospective employee is a citizen of the United States or is a person lawfully authorized to work in the United States. Accordingly, the Department, pursuant to 5 U.S.C. 553(d)(1), has determined that this final rule shall become effective upon May 27, 1980 rather than thirty days thereafter.

This document was prepared under the direction and control of Herbert J. Cohen, Assistant Administrator for Fair Labor Standards, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S-3502, 200 Constitution Avenue, N.W., Washington, D.C. 20210 Telephone 202-523-8353.

The Department of Labor has determined that this is not a major regulation that requires the preparation of a regulatory analysis, within the meaning of Executive Order 12044 and the Department's guidelines published at 44 FR 5570.

Accordingly, § 40.51(p) of Part 40 of Title 29 of the Code of Federal Regulations is amended by adding new paragraphs (p)(1)(vii) through (p)(xii), (p)(4), and (p)(5) to read as set forth below.

Signed at Washington, D.C., on this 22 day of May, 1980.

Donald Elisburg,

Assistant Secretary for Employment Standards.

Ernest G. Green,

Assistant Secretary for Employment and Training.

§ 40.51 Obligations of a farm labor contractor.

* * * * *

(p) * * *

(1) * * *

(vii) Baptismal certificate under seal of a church or other religious body which practices infant baptism showing the individual's date and place of birth within the United States, its territories or possessions.

(viii) A document under seal of a religious body which does not practice infant baptism showing the individual's date and place of birth within the United States, its territories or possessions.

(ix) Tribal enrollment card in an American Indian tribe recognized by the Bureau of Indian Affairs.

(x) Other written advice from The Immigration and Naturalization Service attesting that such person is a citizen of the United States.

(xi) A copy of a declaration, signed by the applicant, under penalty of prosecution for violation of Title 18 U.S.C. § 1001, and witnessed by the signature of the appropriate official of the Employment Service, affixed in the presence of the applicant, filed with the United States Employment Service or any of its affiliated offices attesting that such person is a citizen of the United States, was born at the place stated and on the date set forth thereon, and reciting the following additional information:

(A) Social Security number such (voluntary) and

(B) Names and addresses of three adult citizens of the United States who can be contacted to verify declarant's citizenship.

(xii) A certificate issued by the Department of Labor, Bureau of Employment Security, Commonwealth of Puerto Rico which attests that, based upon examination of any of the documents prescribed by paragraphs (i) through (xi) above, the individual named and identified by the picture on that certificate was born within the United States (including its territories and possessions) at the place and on the date specified thereon and which sets forth such individual's home address (street and number, city, State, zip code) and Social Security number.

* * * * *

(4) Any other written advice from the Immigration and Naturalization Service (INS) that such person is an alien authorized by INS to accept such employment in agriculture in the United States.

(5) United States Armed Forces Discharge Papers.

* * * * *

(Sec. 17, 88 Stat. 1659, (7 U.S.C. 2053); Secretary's Order No., 16-75, 40 FR 55913; and Employment Standards Order 2-75, 40 FR 56743.)

[FR Doc. 80-16181 Filed 5-23-80; 8:45 am]

BILLING CODE 4510-27-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 78-170]

Drawbridge Operation Regulations; Jamaica Bay, NY

AGENCY: Coast Guard, DOT.
ACTION: Final rule.

SUMMARY: At the request of the New York City Department of Transportation and the New York Transit Authority, the Coast Guard will permit the draws of the highway and railroad bridges across Jamaica Bay, North Channel (Grassy Bay), to remain closed to navigation. This change is being made because of infrequent openings of these draws. This action will relieve the bridge owners of the responsibility of supplying draw tenders and of the expense of maintaining the operating machinery.

EFFECTIVE DATE: This amendment is effective on July 1, 1980.

FOR FURTHER INFORMATION CONTACT: Frank L. Teuton, Jr., Chief, Drawbridge Regulations Branch (G-NBR/TP14), Room 1414, Transpoint Building, 2100 Second Street, S.W., Washington, D.C. 20593 (202-426-0942).

SUPPLEMENTARY INFORMATION: On March 1, 1979, the Coast Guard published a proposed rule (44 FR 11566) concerning this amendment. The Commander, Third Coast Guard District, also published this proposal as a Public Notice dated March 28, 1979. Interested persons were given until April 2, 1979 and April 27, 1979, respectively, to submit comments.

DRAFTING INFORMATION: The principal persons involved in drafting this rule are: Frank L. Teuton, Jr., Project Manager, Office of Navigation, and Coleman Sachs, Project Attorney, Office of the Chief Counsel.

Discussion of Comments

Eleven comments were received. Six supported the proposal or had no objection. Five opposed the change on the grounds that: (1) The ability of airport and New York City fire-fighting equipment might be impaired in gaining access to and fighting fires at the Kennedy Airport fuel tank farm. The fire-fighting capacity of airport and New York City marine fire equipment was investigated. The Port Authority of New York and New Jersey maintains an extensive fire-fighting service which is able to control a fire at the Kennedy Airport tank farm. In addition, New York City's fireboats would respond to a fire at the airport fuel facility by way of the Jamaica Bay South Channel. Two of New York City's six fireboats have a height of 25 feet and could pass under the railroad bridge across Jamaica Bay, mile 10.6, so as to reach the area between the two bridges.

(2) Access to the eastern portion of Jamaica bay by high-level vessels might be jeopardized. The New York Towboat and Harbor Carriers Association was contacted and stated that at present no commercial vessels over 55 feet, the height of the fixed bridge across the South Channel of Jamaica Bay, mile 6.0, operate in Jamaica Bay. Bridge logs also show that since 1975 no such vessels have requested bridge openings. Facilities on Jamaica Bay are adequately serviced by vessels whose heights are such that they can utilize the South Channel.

(3) Access between the bridges would be restricted. The closing of these two bridges would restrict the area between the bridges. The greatest vertical clearance offered would be 26 feet above mean high water at the railroad bridge, Jamaica Bay, mile 10.6. Marinas exist between the bridges but none of the vessels at these moorings require bridge openings. In addition, the Corps of Engineers does not maintain a dredged channel through these bridges; Corps vessels operating in Jamaica Bay use the South Channel. Also, should it be necessary for a crane barge to be used between the bridges, access could be gained from the land side. Coast Guard vessels stationed at the Group Rockaway Station, Jamaica Bay, pass under these bridges. There is a sewer treatment plant which uses barges for sludge removal located east of the subject bridges. Sludge barges reach this facility by way of the South Channel and would not be affected by the proposed permanent bridge closures.

In consideration of the foregoing, Part 117 of Title 33 of the Code of Federal Regulations is amended by:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. Revising paragraph (c) of § 117.175 to read as set forth below and by deleting the note after § 117.175(d) because the drawbridge to which it refers is no longer a part of § 117.175.

§ 117.175 Jamaica Bay and connecting waterways, New York.

* * * * *

(c) New York City Department of Transportation highway bridge at Jamaica Bay Boulevard and New York City Transit Authority railroad bridge, both across Jamaica Bay, North Channel (Grassy Bay). The draws of these bridges need not open for the passage of vessels.

* * * * *

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937; 33 U.S.C. 499, 49 U.S.C. 1655(g)(2); 49 CFR 1.46(c)(5))

Dated: May 19, 1980.

Peter J. Rots,

Captain, U.S. Coast Guard, Acting Chief, Office of Navigation.

[FR Doc. 80-16027 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-14-M

VETERANS ADMINISTRATION

38 CFR Part 3

Reduction of Pension Because of Hospitalization

AGENCY: Veterans Administration.
ACTION: Final regulation.

SUMMARY: The Veterans Administration has amended its regulation governing reduction of pension because of hospitalization to include service pension. This action corrects an error that was made when subject regulation was last amended.

EFFECTIVE DATE: This amendment is effective January 1, 1979.

FOR FURTHER INFORMATION CONTACT: T. H. Spindle, Jr. (202-389-3005).

SUPPLEMENTARY INFORMATION: Section 3.551 of title 38, Code of Federal Regulations provides authority and rules for reducing the amount of pension payable to a veteran without dependents who is hospitalized at Veterans Administration expense. Certain changes were made in these rules, effective January 1, 1979, as a result of enactment of Pub. L. 95-588 (92 Stat. 2497) (See 44 FR 45930-44 (1979).)

In amending 38 CFR 3.551 to implement Pub. L. 95-588, however, we unintentionally excluded service pension from its provisions. (Service pension is payable only to Spanish American War veterans.) Consequently, our exclusion of service pension from the provisions of § 3.551 was in error. We have now corrected this error by amending § 3.551 to include service pension. This amendment is being made retroactive to January 1, 1979, since that is the effective date of the prior amendment to § 3.551 that erroneously omitted mention of service pension.

We are not providing for public participation because there has been no statutory or policy change in regard to reduction of service pension because of Veterans Administration hospitalization. This action merely corrects an unintentional error.

The Veterans Administration does not consider this to be a significant proposal since only a small segment of the veteran population is affected and no compliance burdens or costs are imposed.

Approved: May 13, 1980.
By direction of the Administrator.

Rufus H. Wilson,

Deputy Administrator.

Section 3.551 is amended by revising (1) the first sentence of paragraph (a), (2) the heading and the first sentence of paragraph (b), and (3) by changing the heading of paragraph (c) as set forth below:

§ 3.551 Reduction because of hospitalization.

(a) *General.* Pension is subject to reduction when a veteran who has neither spouse, child nor dependent parent is hospitalized, unless the veteran is hospitalized for Hansen's disease. * * *

* * * * *

(b) *Old law pension, and service pension based on entitlement prior to July 1, 1960.* Old law pension, and service pension based on entitlement prior to July 1, 1960, in excess of $30 monthly for a veteran who has neither spouse, child nor dependent parent shall continue at the full monthly rate until the end of the sixth calendar month following the month of admission for hospitalization. * * *

(c) *Section 306 pension, improved pension, and service pension based on entitlement after June 30, 1960.* * * *

[FR Doc. 80-15975 Filed 5-23-80; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[FRL 1487-5]

Redesignation of Attainment Status: Gabbs Valley, Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rulemaking.

SUMMARY: This notice revises the National Ambient Air Quality Standards attainment status designation of the Gabbs Valley area in Nevada from nonattainment to unclassified for total suspended particulates (TSP). Data used to support the initial March 3, 1978 designation were invalid since the monitoring site was unduly influenced by reentrained road dust.

EFFECTIVE DATE: June 26, 1980.

FOR FURTHER INFORMATION CONTACT: Rodney L. Cummins, Chief, Technical Analysis Section, Air Technical Branch, Air & Hazardous Materials Division, 215 Fremont Street, San Francisco, California 90415 (415) 556-2002.

SUPPLEMENTARY INFORMATION: The Clean Air Act Amendments of 1977, Pub. L. 95-95, added Section 107(d) to the Clean Air Act (CAA), which directed each State to submit to the Administrator of the EPA a list of the National Ambient Air Quality Standards (NAAQS) attainment status of all areas within the State. The Administrator was required under Section 107(d)(2) to promulgate the State lists, with any necessary modifications.

For each NAAQS, areas are classified as (1) not attaining the standard or, for certain pollutants, projected not to maintain the standard (nonattainment areas), (2) meeting the standard (attainment areas), or (3) lacking sufficient data or information to be classified (unclassified areas). The EPA published these lists on March 3, 1978 (43 FR 8962). At that time Gabbs Valley was classified nonattainment for TSP.

Under Section 107 of the CAA, either the EPA or the State may initiate changes to the existing designations.

In the February 20, 1980 Federal Register (45 FR 11140), EPA proposed to redesignate the Gabbs Valley area from nonattainment to unclassified for TSP. As discussed in that notice, the data used for the initial March 3, 1978 designation were invalid since the monitoring site was unduly influenced by reentrained road dust.

The February 20, 1978 notice provided a 30 day public comment period. On February 26, 1980, the State of Nevada submitted a letter supporting this redesignation. No other comments were received. Therefore, EPA is redesignating the Gabbs Valley area from nonattainment to unclassified for TSP.

As a result of this redesignation, the State of Nevada is no longer subject to the requirements of Title I, Part D (Plan Requirements for Nonattainment Areas) of the CAA, as amended, for the Gabbs Valley area.

The EPA has determined that this document is not a "significant" regulation and does not require preparation of a regulatory analysis under Executive Order 12044.

(Secs. 107, 301(a), Clean Air Act as amended (42 U.S.C. 7407(d) and 7601(a))

Dated: May 15, 1980.

Douglas M. Costle,

Administrator.

Subpart C of Part 81 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

Subpart C—Section 107 Attainment Status Designations

§ 81.329 [Amended]

1. In § 81.329—Nevada, the attainment status designation table for TSP is amended as follows:

Nevada—TSP

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
* * * * *				
Gabbs Valley	———	———	X	
* * * * *				

[FR Doc. 80-15956 Filed 5-23-80; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 52h

Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects

AGENCY: Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: Final regulations are issued to incorporate the amendment mandated by Pub. L. 95-622, Section 264, enacted on November 9, 1978. The amendment simply expands the scope of the current regulations to include the Division of Nursing of the Health Resources Administration. The HHS Notice of Decision to Amend Regulations, which appeared in the Federal Register of January 23, 1980 (45 FR 5351), stated the Department's intent to promulgate final regulations (without further public participation) because of the technical nature of the change.

EFFECTIVE DATE: May 27, 1980.

FOR FURTHER INFORMATION CONTACT: Dr. Thomas E. Malone, Deputy Director, National Institutes of Health, Bethesda, Maryland 20205 (301) 496-2121.

Accordingly, Title 42 of the Code of Federal Regulations is amended to read as follows:

Dated: April 11, 1980.

Charles Miller,

Acting Assistant Secretary for Health.

Approved: May 20, 1980.

Patricia Roberts Harris,

Secretary.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289*l*-4))

1. Section 52h.1 is revised to read as follows:

§ 52h.1 Applicability.

The regulations in this part apply to:

(a) Applications for grants for biomedical and behavioral research, under the Act to the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Health Resources Adminstration. These regulations do not apply to applications for:

(1) Continuation funding for budget periods within an approved project period;

(2) Supplemental funding to meet increased administrative costs within a project period; or

(3) Construction grants.

(b) Biomedical and behavioral research and development contract projects administered by the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Health Resources Administration.

2. Section 52h.3(b) is revised to read as follows:

§ 52h.3 Establishment and operation of peer review groups.

* * * * *

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director of the National Institutes of Health; the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration; and the Administrator, Health Resources Administration will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9 and 52h.10 within their respective agencies.

3. Paragraph (c) of § 52h.5 is revised to read as follows:

§ 52h.5 Conflict of interest.

* * * * *

(c) Where permissible under the statutes, standards, and order cited in paragraph (a) of this section, the Director of the National Institutes of Health; the Administrator of the Alcohol, Drug Abuse and Mental Health Administration; the Administrator of the Health Resources Administration; or their designees may waive the requirements in paragraph (b) of this section if he or she determines that there is no other practical means for securing appropriate expert advice on a particular grant application, contract project, or contract proposal.

* * * * *

4. Paragraph (c) of § 52h.10 is revised to read as follows:

§ 52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.

* * * * *

(c) The Director of the National Institutes of Health; the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration; the Administrator of the Health Resources Administration; or their designees may identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group in accordance with the provisions of this part and that group has made recommendations concerning the scientific merit of the proposals.

[FR Doc. 80-16024 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-08-M

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45 CFR Part 74

Administration of Grants; Grantee and Subgrantee Audits

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This amends HHS's Department-wide grants administration regulation to implement a recent revision by the Office of Management and Budget (OMB) of the audit standards for governmental recipients of Federal grants and subgrants—Attachment P to OMB Circular No. A-102.

EFFECTIVE DATE: May 27, 1980.

FOR FURTHER INFORMATION CONTACT: Matthias Lasker, Department of Health and Human Services, Room 513D, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, 202-245-7565.

SUPPLEMENTARY INFORMATION: On October 22, 1979, OMB revised its audit standards for States, local governments, and Indian tribal governments under Federal grants and subgrants. The standards formerly appeared in Attachment G, paragraph 2h of OMB Circular No. A-102; they are now located in a new Attachment P, published at 44 FR 60958, 10/22/77.

OMB had previously circulated the proposed revision to interest groups representing governments, to Federal agencies, and to professional associations. OMB also published the proposed revision in the Federal Register (44 FR 40624-5, 7/11/79).

The most significant changes in the audit standards are:

1. OMB has clarified its intent that audits be conducted on an organization-wide basis rather than a grant-by-grant basis.

2. As part of the organization-wide audit concept, the new standards prohibit any Federal program from imposing program specific audit guidelines unless they are approved by OMB.

3. To insure that audits are acceptable to all Federal granting agencies, the new standards establish a cognizant agency system for Federal review of audits.

4. The new standards set forth, in more detail, the prescribed coverage of audits and questions to be answered.

Until now HHS has implemented the audit standards of OMB Circular No. A-102 (governing grants and subgrants to governments) and the audit standards of OMB Circular No. A-110 (governing grants and subgrants to institutions of higher education, hospitals, and private nonprofit organizations) by paraphrasing and combining the text of the two standards. Now, because of the differences between the standards, these amendments simply reference and require compliance with the particular requirements of each OMB circular.

OTHER INFORMATION: These amendments merely require HHS components and HHS grantees and subgrantees to comply with already existing Government-wide policies. For this reason, notice of proposed rulemaking and delay in effective date are considered unnecessary. These amendments are therefore effective on May 27, 1980.

Note.—The Department of Health and Human Services has determined that this document does not contain a major proposal requiring preparation of a Regulatory Analysis under Executive Order 12044.

Dated: May 20, 1980.

Patricia Roberts Harris,

Secretary of Health and Human Services.

Subpart H of 45 CFR Part 74 is amended as follows:

Subpart H—Standards for Grantee and Subgrantee Financial Management Systems and Audits

1. The name of Subpart H is changed to "Standards for Grantee and

Subgrantee Financial Management Systems and Audits."

2. Section 74.60 is revised to read as follows:

§ 74.60 Scope of subpart.

(a) This subpart contains standards for financial management systems and non-Federal audits of recipients.

(b) Awarding parties may not impose on recipients additional financial management standards or requirements concerning non-Federal audits. They may, however, provide recipients with suggestions and assistance on these subjects.

3. Section 74.61 is amended by changing the section heading and by revising paragraph (h), as follows:

§ 74.61 Financial management standards.

* * * * *

(h) *Audit resolution.* Each recipient shall follow a systematic method to assure timely and appropriate resolution of audit findings and recommendations.

4. A new § 74.62 is added to Subpart H, as follows:

§ 74.62 Non-Federal audits.

(a) *Governmental recipients.* Recipients that are governments shall comply with the reqirements concerning non-Federal audits in OMB Circular No. A–102, including any amendments to those requirements published in the Federal Register by OMB.[1]

(b) *All other recipients.* Recipients that are not governments shall comply with the requirements concerning non-Federal audits in OMB Circular No. A–110, including any amendments to those requirements published in the Federal Register by OMB.[1]

[FR Doc. 80-16020 Filed 5-23-80; 8:45 am]
BILLING CODE 4110-12-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 22

Reflecting the Availability of Land Mobile Channels in the 450–512 MHz Band in 13 Urbanized Areas of the United States; Order Setting Date for Filing Formal Agreements

AGENCY: Federal Communications Commission.

ACTION: Requests for time extension for filing formal agreements declared moot.

SUMMARY: The Federal Communications Commission (Commission) has previously amended its regulations to reflect the availability of land mobile channels in the 450–512 MHz band. Applicants who have requested use of these channels must coordinate and/or submit to the Commission formal agreements indicating the technical method by which their systems will operate. The Commission, in Memorandum Opinion and Order (FCC 80–152) released April 23, 1980, established a "coordination period" of 60 days for all parties to submit copies of formal agreements. This order notifies all parties that pending requests for extension of time to file agreements are moot.

DATES: Agreements must be finalized and filed by August 1, 1980.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: John J. Silva, Mobile Services Division, Common Carrier Bureau, Washington, DC 20554, (202) 632–6450.

Order

Adopted May 14, 1980.

Released May 16, 1980.

In the matter of Amendment of Part 21 (now Part 22) of the rules to reflect the availability of land mobile channels in the 450–512 MHz band in 13 urbanized areas of the United States, CC Docket No. 21039.

1. Before the Chief, Mobile Services Division, are motions for extension of time filed by applicants who have requested use of channels in the 450–512 MHz band. The extensions of time are required to allow parties to coordinate and submit to the Commission formal agreements indicating the technical method by which their systems will operate.

2. In paragraph 47 of the Commission Memorandum Opinion and Order (FCC 80–152) released April 23, 1980 (45 FR 29023, 29028, May 1, 1980), the Commission established a "coordination period" which imposed a 60 day deadline for all parties to submit whatever agreements they may have reached.[1]

3. The deadline now established for parties to reach an agreement is August 1, 1980.[2] Because the Commission has already extended the time to file agreements, all individual requests for extension of time are moot.

4. Accordingly, copies of formal agreements must be filed with this Commission, as an amendment to the application, on or before August 1, 1980. A copy of the agreement should be submitted for each application on file and must be signed by all parties who have agreed to the particular method of operation.

Sheldon M. Guttmann,

Chief, Mobile Services Division, Common Carrier Bureau.

[FR Doc. 80-16015 Filed 5-23-80; 8:45 am]
BILLING CODE 6712-01-M

[1] This coordination period applies only to those parties who filed during the initial 60-day filing period.

[2] The 60-day coordination period will commence on the effective date of MO&O FCC 80–152 (June 2, 1980).

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 175

[Docket No. HM–168; Amdt. Nos. 171–55; 175–15]

Hazardous Materials Aboard Aircraft

AGENCY: Materials Transportation Bureau (MTB), Research and Special Programs Administration, Department of Transportation.

ACTION: Final rule.

SUMMARY: This final rule amends certain regulations pertaining to the transportation of hazardous materials aboard aircraft. Specific changes are (1) a restatement of § 175.5 pertaining to the applicability of Part 175 by removing the reference to "civil" aircraft and adding an exception for government-owned aircraft and, with certain limitations, aircraft operated on behalf of a government; (2) a revision to the exception in § 175.5, for aircraft of United States registry under lease to and operated by foreign nationals outside the United States; (3) the adoption of a new § 175.31 to require the reporting of certain discrepancies in hazardous materials shipments detected following the acceptance of shipments for transportation aboard aircraft; and (4) a revision of § 175.85 to provide clarification of the term "accessible" and to exclude certain classes of materials from the accessibility requirements of the section.

EFFECTIVE DATE: October 1, 1980.

FOR FURTHER INFORMATION CONTACT: Edward T. Mazzullo, Office of Hazardous Materials Regulation, Materials Transportation Bureau, Research and Special Programs Administration, U.S. Department of Transportation, Washington, D.C. 20590, (202) 426–2075.

SUPPLEMENTARY INFORMATION: On December 11, 1978, the MTB published a notice of proposed rulemaking (Docket HM–168, Notice 78–13; 43 FR 57928) which addressed four issues involving the transportation of hazardous materials aboard aircraft. The MTB's

actions and significant public comments concerning the proposals contained in the Notice are discussed in the following paragraphs.

Applicability of Part 175. There has been much confusion concerning the applicability of the Hazardous Materials Regulations (HMR) to nongovernment-owned aircraft which are "used exclusively" by a government. In order to lessen the possibility of noncompliance due to any misunderstanding, the MTB has determined that it is necessary to clarify the applicability of the HMR in this area. This amendment prescribes the requirements which define exclusive direction and control (by a government) of nongovernment-owned aircraft to provide a clear distinction between the applicability and inapplicability of regulations issued under the Hazardous Materials Transportation Act, (HMTA) (49 U.S.C. 1801 *et seq.*).

The proposal contained in Notice 78–13 has been adopted with certain revisions. The changes include a shortening of the prescribed minimum lease period from 180 days to 90 days and an editorial revision of § 175.5 for the purpose of clarity.

The proposal to delete the word "civil" from Appendix B of Part 107 was handled in the final rule to Docket HM–166B (45 FR 13087: February 28, 1980).

Four comments submitted by certain Federal agencies criticized the proposal to require that aircraft be chartered or leased for a minimum of 180 days as a condition of exclusive use. Two of the commenters requested periods of 30 days or 60 days on the premise that the shorter periods are more in keeping with their current utilization of leased aircraft. Upon review of submitted data concerning aircraft utilization, the MTB has reduced the minimum lease period to 90 days. It is believed that this change will cover the majority of these government leasing arrangements, thus easing the burden of compliance on the agencies involved. It is the MTB's opinion that a stipulated leased period of less than 90 days would be inconsistent with the intent of this rulemaking action.

Two of the critical commenters suggested that any minimum lease period is unacceptable. One suggested that any shipment accompanied by a government courier or custodian should be excepted from the HMR. The MTB disagrees with this suggestion. The accompaniment of a shipment by a government representative is, of itself, irrelevant with regard to determining the applicability of the HMR to the shipment. The other commenter contended that the operations of a government agency are not in commerce and hence not subject to the HMR. The MTB disagrees with this contention. For transportation by aircraft, a government's hazardous materials shipments are subject to the HMR (1) when the government uses aircraft (civil or private) for commercial purposes (as in the case of certain foreign airlines which operate within the United States and are owned by foreign governments); and (2) when a government uses a nongovernment-owned aircraft which is not established as being under its exclusive direction and control.

One commenter suggested that provision be made to except government-owned, contractor-operated aircraft from compliance with the HMR. The MTB does not believe it necessary to incorporate the suggested provision. If government-owned aircraft are operated exclusively within the government's own sphere of activities for non-commercial purposes, regulations issued under the HMTA do not apply to such operations. Non-commercial operations are conducted by certain Federal, state and local government agencies and by government subdivisions such as state universities.

Aircraft Leased to Foreign Nationals. This action is taken in recognition of an obligation of the United States under the Chicago Convention. Chapter 3.5, Annex 6, Part 1 of the Convention provides that explosives and other dangerous articles, except where necessary for operation, navigation or safety of an aircraft, may only be carried if their carriage is approved by the aircraft's state (nation) of registry and they are in conformance with the regulations of that state.

Prior to this amendment, Part 175 did not apply to aircraft of United States registry which were under lease to and operated by foreign nationals outside the United States. Historically, the exception was included in the regulations in recognition of the difficulty the U.S. Federal Aviation Administration has had in obtaining compliance with Part 175, and other parts of the HMR which are incorporated by reference in Part 175, in those operations. Unfortunately, the language of the exception did not include a requirement that an equivalent body of regulations must be complied with in lieu of Part 175 to insure that United States obligations under Annex 6 of the Chicago Convention would be met. Determinations of equivalency pose significant problems due to differing requirements. Moreover, there could be many instances where insufficient time would be available in a leasing transaction to compare the HMR with the requirements and prohibitions of another state.

To remedy the situation, the exception in § 175.5 has been revised to stipulate that the HMR do not apply to United States registered aircraft under lease to and operated by foreign nationals outside the United States if (1) hazardous materials are carried in accordance with the pertinent regulations of the state of the foreign operator, and (2) the materials are not forbidden aboard aircraft by § 172.101. The amendment on this subject represents a substantial revision of the proposal contained in Notice 78–13 which would have required full compliance with the HMR by foreign operators. The revision is based on the merits of several comments to the docket which addressed the inability of foreign operators to comply with requirements of the HMR. Commenters contended that, in many instances, compliance with the HMR would place them in conflict with national or international regulations applicable to the operations of foreign operators. Further, they contended that it would be difficult, if not impossible, to obtain compliance with the HMR by foreign shippers offering hazardous materials for shipment totally outside the United States. The MTB believes these comments have merit and the revision which has been adopted alleviates these difficulties while satisfying United States obligations under the Chicago Convention.

While the MTB has no assurance that the regulations of the nation of a foreign operator will always achieve a level of safety equivalent to that provided by the HMR, it believes the amendment to be the best and most practical solution to the problem. Several comments addressed the difficulty of enforcing any requirement which would apply to foreign operators. Enforcement could, admittedly, be difficult in some instances. However, the requirement is considered necessary and there are means available to the FAA for legal recourse against U.S. lessors, foreign operators, and their agents. Since many of the materials prohibited for air transportation by the HMR are also banned by other governments, it is not anticipated that there will be significant problems involving non-compliance with the prohibitions. It is also anticipated that U.S. lessors may desire to stipulate compliance with the new provision as part of their leasing agreements.

It should be noted that the International Civil Aviation Organization is presently drafting a new Annex entitled "Safe Transport of

Dangerous Goods by Air" and that this Annex will be considered by the MTB when it is issued. It is anticipated that § 175.5 will require further amendment at that time.

Reports of Discrepancies. This requirement is based on a petition from the Air Line Pilots Association (ALPA), and a similar proposal contained in National Transportation Safety Board (NTSB) Safety Recommendation A–74–26, to require that an aircraft operator report each instance a package offered to the operator for transport by air is discovered not in compliance with the HMR. The proposal contained in Notice 78–13 has been adopted with certain revisions.

The NTSB, in its comments on Docket HM–168, contended "* * * that none of the MTB's actions to date have corrected the deficiency in the existing system which permits a shipper to seek acceptance of a shipment by other carriers once it has been refused by a carrier because of noncompliance with Federal standards." The NTSB further stated "The Safety Board urges the MTB to take action to insure that carriers are required to hold a shipment and its papers until the FAA is notified and the shipment is corrected." Although the MTB agrees with the spirit of this recommendation, the HMTA does not grant the MTB authority to confer upon private individuals (aircraft operators and carriers) the authority to confiscate (in effect) the property of another individual based on presumed, though not proven, noncompliance with the HMR.

In addition to what the MTB considers to be legal impediments to this recommendation, there are practical impediments as well. It would be extremely difficult for FAA enforcement personnel to deal with discrepancy notifications involving potential shipments prior to their acceptance by aircraft operators. A shipment containing a hazardous material must be offered to the carrier in accordance with the regulations. An offering occurs when (1) the package is presented, (2) the shipping paper is presented, (3) the certification is executed, and (4) the transfer of the package and shipping paper is completed with no further exchange (written or verbal) between the shipper and aircraft operator, as usually evidenced by the departure of the shipper. At this point, it is clear that the operator has accepted the shipment and the shipper has removed himself from a final opportunity to take corrective action that would preclude a violation of the HMR relative to transportation of hazardous materials aboard aircraft. Absent a clear showing that the package was offered for transportation as illustrated above, the MTB doubts that an effective enforcement action could be taken against persons who appear at airline cargo terminals seeking to ship packages of hazardous materials.

Based on impediments to implementation of a more comprehensive reporting requirement, the requirement which has been adopted limits required reporting to shipment discrepancies which are discovered subsequent to acceptance of the shipment for transportation and limits "reportable" discrepancies to those discrepancies which are not detectable as a result of proper examination by a person accepting the shipment under the acceptance criteria of § 175.30.

This notification requirement will facilitate the timely investigation by FAA personnel of shipment discrepancies involving situations where inside containers do not meet prescribed packaging or quantity limitation requirements and where packages or baggage are found to contain hazardous materials after having been offered and accepted as other than hazardous materials.

Accessibility. The purpose of this change is to define the term "accessible" as used in § 175.85(b) and to except certain materials from accessibility requirements. The definition is considered necessary because there has been confusion in the past over the meaning of the term "accessible." Certain materials have been excepted from accessibility requirements because they pose no significant risks to the structural integrity of an aircraft and may be safer to carry in inaccessible locations that are not in proximity to crewmembers.

The proposal contained in Notice 78–13 has been adopted with revisions. It should be noted that radioactive materials were excepted from accessibility requirements prior to this amendment in Docket HM–168, Amendment 175–11 (45 FR 6946) published on January 31, 1980. The reasons for this action are explained in the preamble to Amendment 175–11.

The types of materials which are excepted from accessibility requirements have been expanded to include not only radioactive, poison B and irritating materials but also etiologic agents. The change is based on the merits of comments by ALPA to the effect that infectious, disease producing agents should be carried as far away from the flight crew as possible. The MTB has revised the proposed exception to permit packages suitable for passenger-carrying aircraft to be transported inaccessibly on cargo-only aircraft in quantities exceeding the quantity limitation (50 lb. net weight per inaccessible cargo compartment or freight container) imposed by § 175.75(a)(2). Without this provision packages containing quantities permitted on passenger-carrying aircraft would be subject to more restrictive location requirements on cargo-only aircraft than packages of identical materials containing larger, cargo-only aircraft, quantities.

The exception from accessibility requirements provided for small, single pilot, cargo-only aircraft being used where other means of transportation are impracticable or not available has been retained in this amendment but has been relocated from paragraph (b) to paragraph (c) in § 175.85.

Based on the merits of comments by an aircraft operator in Alaska, an additional exception from the accessibility requirements of § 175.85(b) has been provided. This exception applies to cargo-only aircraft being operated where other means of transportation are impracticable or not available and will permit operators of such aircraft to deviate from accessibility requirements to the extent that they may use alternate cargo stowage procedures where such procedures are reviewed prior to implementation and approved in writing by an appropriate FAA field office. The exception addresses those situations in which large packages are carried in quantities necessitating the stowage of some of the packages in locations on the aircraft where they cannot be readily handled and separated from other cargo during flight, such as when aircraft loads of 55 gallon drums of hazardous materials are carried.

The above-mentioned changes have necessitated a format revision of § 175.85. Paragraph (b) now contains only the requirement that cargo be carried accessibly. Former paragraph (c) has been redesignated paragraph (f) and a new paragraph (c) has been added which contains certain exceptions to the requirements of §§ 175.85(b) and 175.75(a).

Comments to the docket indicated some misunderstanding of the accessibility requirements. First, this final rule is a clarification, rather than a significant revision, of accessibility requirements. The MTB has never considered it acceptable to load materials acceptable only for cargo-only aircraft in inaccessible locations on aircraft such as inaccessible cargo compartments, inaccessible freight containers or, for packages located in

accessible cargo compartments, in locations making them inaccessible. Second, this final rule does not preclude the use of either pallets or freight containers. Pallets may be used, within the context of § 175.85(b), if at least one side or end of each palletized package containing hazardous materials is visible and it is possible to handle and separate packages during flight, if necessary.

In order to render palletized packages visible and separable, it may not be feasible to load pallets to full capacity. However, lost pallet capacity may be minimized by leaving open areas in the middle of pallets so that interior packages are rendered visible, or by using packages of other than hazardous materials as interior packages on pallets.

With regard to freight containers, such containers may be used within the context of § 175.85(b), if the containers are loaded in a manner that permits inspection of their contents during flight, and if each package of hazardous materials contained therein is loaded accessibly, that is, it can be seen, handled and separated from other cargo during flight. By the same token, nonstructural containers and insulating or padding materials are not precluded from use as long as covered packages can be readily inspected, handled and separated from other cargo during flight.

One commenter has suggested that a definition of "accessible" proposed in the ICAO Annex 18 entitled "Safe Transport in Dangerous Goods by Air" be made part of the HMR. The MTB will give consideration to Annex 18 in its entirety at a future date. Because of this, and because of differences between the ICAO proposed definition and the definition proposed in Notice 78-13, a verbatim adoption of the ICAO definition would not be appropriate at this time.

In consideration of the foregoing, Parts 171 and 175 of Title 49 are amended as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

§ 171.8 [Amended]

1. Section 171.8 is amended by deleting the definitions for "Civil aircraft" and "Public aircraft."

PART 175—CARRIAGE BY AIRCRAFT

2. Section 175.1 is revised to read as follows:

§ 175.1 Purpose and scope.

This part prescribes requirements, in addition to those contained in Parts 171, 172 and 173 of this subchapter, applicable to aircraft operators transporting hazardous materials aboard (including attached to or suspended from) aircraft.

3. Section 175.5 is revised to read as follows:

§ 175.5 Applicability.

(a) This part applies to the acceptance for transportation, loading and transportation of hazardous materials in any aircraft in the United States and in aircraft of United States registry anywhere in air commerce. This part does not apply to—

(1) Aircraft owned and operated by a government when not engaged in carrying persons or property for commercial purposes;

(2) Aircraft which are not owned by a government nor engaged in carrying persons or property for commercial purposes but which are under the exclusive direction and control of a government for a period of not less than 90 days as specified in a written contract or lease. An aircraft is under the exclusive direction and control of a government when the government exercises responsibility for—

(i) Approving crew members and determining that they are qualified to operate the aircraft;

(ii) Determining the airworthiness and directing maintenance of the aircraft; and

(iii) Dispatching the aircraft, including the times of departure, airports to be used, and type and amount of cargo to be carried;

(3) Aircraft of United States registry under lease to and operated by foreign nationals outside the United States if—

(i) Hazardous materials forbidden aboard aircraft by § 172.101 of this subchapter are not carried on the aircraft; and

(ii) Other hazardous materials are carried in accordance with the regulations of the State (nation) of the aircraft operator.

4. Section 175.31 is added to read as follows:

§ 175.31 Reports of discrepancies.

(a) Each person who discovers a discrepancy, as defined in paragraph (b) of this section, relative to the shipment of a hazardous material following its acceptance for transportation aboard an aircraft shall, as soon as practicable, notify the nearest FAA Air Transportation Security Field Office by telephone and shall provide the following information:

(1) Name and telephone number of the person reporting the discrepancy.

(2) Name of the aircraft operator.

(3) Specific location of the shipment concerned.

(4) Name of the shipper.

(5) Nature of discrepancy.

(b) Discrepancies which must be reported under paragraph (a) of this section are those involving hazardous materials which are improperly described, certified, labeled, marked, or packaged, in a manner not ascertainable when accepted under the provisions of § 175.30(a) of this subchapter, including—

(1) Package which are found to contain hazardous materials—

(i) Other than as described or certified on shipping papers;

(ii) in quantities exceeding authorized limits;

(iii) In inside containers which are not authorized or have improper closures;

(iv) In inside containers not oriented as shown by package markings;

(v) With insufficient or improper absorption materials, when required; or

(2) Packages or baggage which are found to contain hazardous materials subsequent to their being offered and accepted as other than hazardous materials.

5. In § 175.85, paragraph (b) is revised, paragraph (c) is redesignated as paragraph (f), and a new paragraph (c) is added as follows:

§ 175.85 Cargo locations.

* * * * *

(b) Each person carrying a package containing a hazardous material acceptable only for cargo-only aircraft shall carry the package in a location accessible to a crewmember during flight. To be considered accessible, the package must be loaded in such a manner that it can be seen, handled, and separated from other cargo during flight.

(c) Notwithstanding the provisions of paragraph (b) of this section—

(1) When packages of the following hazardous materials are carried on cargo-only aircraft, they may be carried in a location which is inaccessible to a crewmember during flight and are not subject to the weight limitation specified in paragraph (a)(2) of § 175.75 of this subchapter.

(i) Radioactive materials,

(ii) Poison B, liquids or solids (except those labeled FLAMMABLE),

(iii) Irritating materials, and

(iv) Etiologic agents.

(2) When packages of hazardous materials acceptable for cargo-only or passenger-carrying aircraft are carried on cargo-only aircraft where other means of transportation are impracticable or not available, packages may be carried in accordance with procedures approved in writing by the

FAA Air Transportation Security Field Office responsible for the operator's overall aviation security program or the FAA Air Transportation Security Division in the region where the operator is located.

(3) When packages of hazardous materials acceptable for cargo-only or passenger-carrying aircraft are carried on small, single pilot, cargo-only aircraft being used where other means of transportation are impracticable or not available, they may be carried without quantity limitation as specified in § 175.75 in a location that is not accessible to the pilot if—

(i) No person other than the pilot, an FAA inspector, the shipper or consignee of the material or a representative of the shipper or consignee so designated in writing, or a person necessary for handling the material is carried on the aircraft;

(ii) The pilot is provided with written instructions on characteristics and proper handling of the materials; and

(iii) Whenever a change of pilots occurs while the material is on board, the new pilot is briefed under a hand-to-hand signature service provided by the operator of the aircraft.

* * * * *

(49 U.S.C. 1803, 1804, 1808; 49 CFR 1.53 and App. A to Part 1)

Note.—The Materials Transportation Bureau has determined that this document will not result in a major economic impact under the terms of Executive Order 12044 and DOT implementing procedures (44 FR 11034) nor require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321 et seq.). A regulatory evaluation is available for review in the docket.

Issued in Washington, D.C., on May 15, 1980.

L. D. Santman,

Director, Materials Transportation Bureau.

[FR Doc. 80-15990 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-60-M

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 80-01; Notice 2]

New Pneumatic Tires for Passenger Cars; Federal Motor Vehicle Safety Standards

AGENCY: National Highway Traffic Safety Administration, Department of Transportation.

ACTION: Final rule.

SUMMARY: Pursuant to petitions by the Rubber Manufacturers Association (RMA) and the European Tyre and Rim Technical Organization (ETRTO), this notice amends Federal Motor Vehicle Safety Standard No. 109, *New Pneumatic Tires—Passenger Cars*, by adding certain tire size designations to Appendix A of that Standard. This notice also corrects a typographical error made by RMA concerning the test rim width for a tire size. This amendment permits the introduction into interstate commerce of the new tire sizes.

EFFECTIVE DATE: June 26, 1980, if objections are not received before that date.

ADDRESS: Comments should refer to Docket No. 80-01 and be submitted to Docket Section, Room 5108, 400 Seventh Street, SW., Washington, D.C. 20590. (Docket hours are 8 a.m. to 4 p.m.).

FOR FURTHER INFORMATION CONTACT:

John Diehl, Office of Automotive Ratings, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, D.C. 20590 (202-426-1714).

SUPPLEMENTARY INFORMATION:

According to agency practice, the National Highway Traffic Safety Administration (NHTSA) responds to petitions for adding new tire sizes to Table I of Appendix A of Standard No. 109 by quarterly issuing final rules under an abbreviated rulemaking procedure for expediting such routine amendment. Guidelines for this procedure were published at 33 FR 14964; October 5, 1968, and amended at 36 FR 8298; May 4, 1971, 36 FR 13601; July 22, 1971, and 39 FR 28990; August 13, 1974. These guidelines provide that these final rules become effective 30 days after their date of publication in the Federal Register if no comments objecting to them are received by NHTSA during this 30 day period. If objections are received, regular rulemaking procedures for issuing and amending motor vehicle safety standards are initiated.

On February 19, 1980, ETRTO petitioned for the addition of two new tire sizes to an existing table within Table I of Appendix A of Standard No. 109. On March 11, 1980, RMA petitioned for the addition of a new tire size to an existing table. Additionally, on February 20, 1980, RMA filed a petition stating that there was a typographical error in data they have previously submitted to this agency, and asked that the error be corrected.

The basis for accepting or denying requests to add new tire size designations are set forth in the introductory guidelines to Appendix A. Briefly, the tests are the appropriateness of the information submitted for inclusion in the tire tables of the requested tire sizes. The three new tire size designations requested to be added to Standard No. 109 appear to meet these criteria. Accordingly, the RMA and ETRTO petitions are granted, and three new tire sizes are added to Table I of Appendix A of the Standard pursuant to the abbreviated rulemaking procedures. Additionally, the RMA request to correct a typographical error by that organization in its prior submission is granted, and the correction is made.

In consideration of the foregoing, 49 CFR 571.109 is amended as specified below, subject to the 30-day comment period outlined below.

§ 571.109 New pneumatic tires—passenger cars [appendix amended]

1. Tables I-DD and I-LL are amended by adding the following new tire size designations and corresponding values:

Table I-DD.—*Tire Load Ratings, Test Rims, Minimum Size Factors, and Section Widths for "55 Series" Radial Ply*

Tire size[1] designation	Maximum tire loads (pounds) at various cold inflation pressures (pounds per square inch)													Test rim width (inches)	Minimum size factor (inches)	Section width[2] (inches)
	16	18	20	22	24	26	28	30	32	34	36	38	40			
195/55R15	685	730	775	815	855	895	935	970	1,005	1,040	1,075	1,110	1,140	6	30.85	7.91
275/55R15	1,260	1,350	1,430	1,500	1,580	1,650	1,720	1,790	1,860	1,920	1,980	2,040	2,100	8	37.19	10.96

[1] The letter "H", "S" or "V" may be included in any specified tire size designation adjacent to the "R."

[2] Actual section width and overall width shall not exceed the specified section width by more than 7 percent.

Table I-LL.—*Tire Load Rating, Test Rims, Minimum Size Factors and Section Widths for T/80 Series 60 lb/in² Tires*

Tire size[1] designation	Maximum tire loads (pounds at 60 lb/in² cold inflation pressure)									Test rim width (inches)	Minimum size factor (inches)	Section width (inches)
	—	—	—	—	—	—	—	—	—			
T105/80D13					60 lb/in². 1,036 lbs.					4	23.78	4.57

[1] The letters "D" for diagonal and "B" for bias belted may be used in place of the "R."
[2] Actual section width and overall width shall not exceed the specified width by more than the amount specified in §4.2.2.2.

2. Table I-KK is amended, with the following values substituted for the P195/60R14 tire size:

Table I-KK.—*Tire Load Rating, Test Rims, Minimum Size Factors and Section Widths for P/60 Series ISO Type Tires*

Tire size[1] designation	Maximum tire loads (kilograms) at various cold inflation pressures (kPa)									Test rim width (inches)	Minimum size factor (mm)	Section[2] width (mm)
	120	140	160	180	200	220	240	260	280			
P195/60R14	365	395	420	445	470	495	515	540	560	5½	773	196

[1] The letters "D" for diagonal and "B" for bias belted may be used in place of the "R."
[2] Actual section width and overall width shall not exceed the specified width by more than the amount specified in § 4.2.2.2.

Interested persons are invited to submit comments on these additions. Comments must be limited so as not to exceed 15 pages in length. Necessary attachments may be appended without regard to the 15 page limit. This limitation is intended to encourage commenters to detail their primary comments in a concise fashion. Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

The agency has reviewed the impacts of this rule, and determined that permitting the introduction of these tire sizes will benefit those manufacturers desiring to produce the sizes and will have no effect on those manufacturers who do not. The public will be minimally affected by this rule. Accordingly, NHTSA has determined that this is not a significant regulation within the meaning of Executive Order 12044.

The program official and attorney responsible for the development of this rule are John Diehl and Stephen Kratzke, respectively.

(Secs. 103, 119, 201, and 202, Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392, 1407, 1421, and 1422); delegations of authority at 49 CFR 1.50 and 49 CFR 501.8)

Issued on May 19, 1980.

Carl Nash,

Acting Associate Administrator for Rulemaking.

[FR Doc. 80-15826 Filed 5-23-80; 8:45 am]
BILLING CODE 4910-59-M

Proposed Rules

Federal Register
Vol. 45, No. 103
Tuesday, May 27, 1980

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 274

[Amdt. No. 171]

Food Stamp Program—Food Stamp Issuance and Participation Reporting System

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rulemaking changes the State reporting of food stamp issuance and participation data to improve control over the obligation of food stamp appropriations. The changes also reduce the Federal reporting burden on States. The proposal introduces a new Form FNS–388, State Coupon Issuance and Participation Estimates, and revises and reduces the reporting requirements for the Form FNS–256, Project Area Participation and Coupon Issuance. The Department anticipates that the changes will improve the current reporting systems and provide for more effective fiscal controls through more timely State reports.

DATE: Comments must be received on or before July 28, 1980, in order to be assured of consideration. After reviewing all comments, we will publish final regulations.

ADDRESS: Comments should be submitted to: Alberta C. Frost, Deputy Administrator for Family Nutrition Programs, Food and Nutrition Service, USDA, Washington, D.C. 20250. All written comments will be open to public inspection at the offices of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at Room 678, 500 12th Street SW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Susan McAndrew, Chief, Program Standards Branch, Program Development Division, Food and Nutrition Service, Washington, D.C. 20250. Phone (202) 447–6535. The Draft Impact Statement describing the options considered in developing this proposed rule and the impact of implementing each option is available on request from the above named individual.

SUPPLEMENTARY INFORMATION: This proposed action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified "not significant".

Introduction

The Department is proposing to revise its present systems for reporting food stamp issuance and program participation data by States. These changes are being made to improve the timeliness and accuracy of issuance and participation data used in: (1) Measuring the use and availability of food stamp bonus funds; (2) making decisions regarding benefit reductions which may be required to avoid incurring obligations in excess of appropriations; and (3) reporting nationwide program obligations and participation to Congress and the general public.

The Secretary's decision as to whether or not program benefits must be reduced to keep program spending within the amounts appropriated is based on reported actual coupon issuance plus projected issuance for the remainder of the fiscal year. Section 18 of the Food Stamp Act of 1977 (as amended, P.L. 96–58, 93 Stat. 389, Aug. 14, 1979), requires the Department to submit to the House and Senate Agriculture committees by the 15th of each month a report of the best estimates of the second preceding month's expenditures and whether there is reason to believe that reductions in future allotments will be necessary. The timeliness and accuracy of the data available to the Secretary when submitting this report will have a direct effect upon this decision.

In fiscal year 1979, the real possibility of a benefit reduction existed until supplemental funding was provided. The Department faces a larger potential funding shortage this fiscal year. The proposed system of reporting will provide the Department with a documented, timely and consistent basis for recording and reporting food stamp obligations and an improved process for projecting future obligations. The new reporting processes are essential to support actions to avoid overobligation of available appropriations while at the same time permitting any reduction to be tailored as closely as possible within funds available.

Task Force Involvement

Prior to preparing this regulatory proposal, the Department established a task force consisting of Federal and State personnel.

The task force analysis, recommendations and pilot test results have served as the foundation for the proposed regulations. Ten State agencies, all FNS Regional Offices, the FNS National Office and the Department's Office of Budget, Planning and Evaluation were represented on the task force. The States selected for participation were chosen because of their diverse size, the variety of coupon issuance systems which they represent and the variety of organizational approaches to program administration they use. The task force further solicited comments from other State agencies and members of the American Public Welfare Association.

As a result of a thorough review of present reporting systems, the task force concluded that current reports do not provide the data needed on a sufficiently timely basis. The FNS–250, Food Stamp Accountability Report and the FNS–256, Project Area Participation and Coupon Issuance report provide actual value of coupons issued and participation. These reports are due to FNS 45 days after the report month, and experience has demonstrated that many States need 45 days to provide the reports. Also, since approximately 9,000 reporting points submit these reports, collection and processing of all reports requires additional time in the Food and Nutrition Service. The existing reporting systems do not provide financial and participation data on a sufficiently timely basis to meet Office of Management and Budget and Congressional reporting requirements.

Proposed FNS–388

In order to obtain the more timely data necessary to meet the requirements of the Food Stamp Act Amendments of 1979 (Pub. L. 96–58), the Department proposes a new monthly Form FNS–388, State Coupon Issuance and Participation Estimates. The FNS–388 would provide State level coupon issuance and

participation estimates for the current month and revised estimates for the preceding month. (A copy of this report is attached for comment).

The proposed FNS–388 reporting process would provide FNS with timely issuance and participation data in order to estimate fiscal year-to-date issuance and participation to be used in making the decision on benefit reductions. State agencies would telephone the FNS–388 Report data to the Regional Office no later than the close of business on the 19th of each month. The Regional Office would in turn, telecopy or telephone the data to the National Office no later than close of business on the 20th. The State agency would follow-up the telephone call with a hard copy of the report. Regional Offices would also follow-up the telecopied or telephoned data with a hard copy report reconciled to the State hard copy reports.

This process provides FNS with an estimate of the issuance and participation from every State by the 20th of the month for that month. FNS will use these estimates and the actual issuance and participation data from the FNS–250 and FNS–256 Reports, respectively, to arrive at nationwide, fiscal year-to-date issuance and participation estimates by approximately the 25th of the month. Finally, FNS would use these nationwide, fiscal year-to-date estimates of issuance and participation in the process of deciding whether a benefit reduction is required.

Estimation Procedures

States will be permitted to individually choose their best source of data and develop their own estimation procedures based upon their coupon issuance system and unique organizational structure within the State.

The methodology developed by the States would be reviewed by FNS to assure that the methodology will provide the necessary data within established accuracy standards and required time frames.

The purpose for establishing accuracy standards is to provide States with a bench mark against which they can measure their own performance based on established tolerance levels. The accuracy standards will alert States to the need for refining their methodologies when the tolerance levels are exceeded.

The following guidelines were recommended by the task force as sources and methods of obtaining the data required in the FNS–388 Report.

1. *Current Month's Estimated Coupon Issuance (Dollars).—*

- States with automated ATP card production systems should use ATP production lists as of a certain date, e.g., the 15th of the current month, to obtain a statewide estimate of the total dollar value of all cards to be issued during that month. The predicted card issuance estimate should be adjusted for significant factors (e.g., non-participation and manual issuance) to arrive at estimated statewide coupon issuance. For State supervised programs with decentralized ADP systems, the dollar value of the statewide ATP card issuance estimate may be based on ATP production data from a sampled number of project areas.
- States with automated mail issuance systems should use mail issuance lists of total coupon issuance as of a certain date and adjust the statewide estimate for significant factors (e.g., returned coupons) to obtain a projected total coupon issuance amount for the current month. For State supervised programs, the statewide coupon issuance estimate may be based on data from a sample number of project areas.
- States with manual HIR, ATP card production, or mail issuance system should project current month's coupon issuance based on coupon issuance data from sampled project areas.
- States that have more than one type of issuance system should choose the method(s) described above which provides the most accurate estimate.

2. *Previous Month's Estimated Coupon Issuance (Dollars).—* Recommended sources and methods of obtaining the dollar estimate of previous month's coupon issuance are:

- States with automated ATP card production systems should use actual coupons issued based on coupon inventory or issuance records States might selectively sample reporting points to obtain a sample estimate of issuance which would then be projected to the total state.
- States with automated ATP card production systems could also use the latest ATP production lists to obtain a statewide estimate of the total dollar issuance value of all cards issued last month. This estimate should be adjusted for significant factors (e.g., non-participation) to determine statewide coupon issuance. For State supervised programs with decentralized ADP systems, States might selectively sample project areas to project the dollar value of statewide ATP card issuance data.
- States with automated or manual mail issuance systems, manual ATP card production systems, or manual HIR systems should use actual coupons issued data based on coupon inventory or issuance records. States might selectively sample reporting points to obtain a sample estimate of the dollar value of issuance which would then be projected to the total State.
- States that have more than one type of issuance system should use the method(s) decribed above that provide the most accurate estimate.

3. *Current Month's Estimated Number of Participating People.—*If the State agency can estimate the number of households and can also estimate the average number of people per houshold based on historical data, it can then calculate number of people by multiplying these two numbers. If the State agency can estimate the average dollar issuance per person based on historical data, then it can calculate number of people by dividing total dollar issuance by average dollar issuance per person.

4. *Previous Month's Estimated Number of Participating People.—*The number of people who participated last month can be calculated in the same way that the current month's estimate of number of people is calculated.

5. *Current Month's Estimated Number of Participating Households.—*For States that use ATP card production lists in estimating coupon issuance, the number of households can be estimated based on the number of ATP cards issued. For States that use mail issuance production lists to estimate coupon issuance, the number of households might be estimated based on the number of households in the list. For States that use historical data to estimate dollar issuance, historical data might be used to estimate number of households.

6. *Previous Month's Estimated Number of Participating Households.—* For States that use ATP card production lists to estimate dollar issuance, the number of ATP cards issued can be used for estimating number of households. For States that use coupon inventory or issuance records, historical participation data can be used for estimating the number of households.

Since State systems vary, the regulations do not mandate a particular methodology. A State's estimation methodology should be based on the ability of the methodology chosen by the State to produce timely and accurate data on a consistent basis. States which have participated in the pilot testing of the FNS–388 report, as well as FNS national and regional representatives, will be available to assist other States in developing an effective estimation methodology.

Accuracy Standards

FNS proposes the following accuracy standards (deviations of the estimates from actuals) for the estimated issuance and participation data on the FNS-388 Report for States' use:

(1) *Standard for "Current Month" issuance and participation data.*—The current month statewide estimates for the coupon issuance amount (in dollars) and the participation figures (number of households and number of people) shall be within ± 4% of the actual amounts.

(2) *Standard for "Last Month" issuance and participation data.*—The last month statewide estimates for coupon issuance and participation shall be within ± 2% of the actual amounts.

On a monthly basis, FNS will measure the accuracy for coupon issuance by comparing the FNS-388 to the cumulative sum of line 19 from the FNS-250 reports from all issuance agents in the State. To measure the accuracy of the participation data, FNS will rely on the data available from the FNS-256 report.

Therefore, it will remain essential even after the introduction of the FNS-388 for timely and accurate reporting on the FNS-250 and FNS-256 reports. Late or inaccurate reports could cause a State to be out of tolerance with that month's accuracy standard for the FNS-388. Experience with the pilot States indicates that these accuracy standards can be met within one or two months of operating experience. However, FNS would like comment on the reasonableness of these standards. In developing comments, keep in mind the use to which the data will be put. Suggestions as to alternative data sources against which to measure the accuracy of the FNS-388 would also be of use.

Recommendations for State Automated Issuance Systems

FNS recognizes that the degree of automation and design of issuance systems varies from State to State. When the pilot States were developing their FNS-388 estimation procedures, FNS encouraged them to develop procedures that were most satisfactory for their particular issuance systems. For States that are currently modifying or developing new automated systems, FNS would like to present a design recommendation for State agency consideration. FNS believes that the State's implementation of this recommendation would enhance the State's capabilities to provide more accurate and timely FNS-388 estimates. Implementation of this recommendation might also assist the States to better manage and report on their food stamp program. FNS recommends that States include in their automated systems the capability to capture, sum and report by month on the amount of (1) issuance dollars, (2) participating people, and (3) participating households. To facilitate FNS-388 reporting, the automated system should be capable of capturing, summing, and reporting these data elements at the time the ATP cards or mail issuance authorizations are printed as well as after the full month's issuance transactions have occurred. If the States' automated system cannot capture and report on all three items, then it should report issuance dollars and either participating people or participating households, preferably participating people.

It is not expected that all automated systems be designed to include the totality of issuance authorizations during the month. Many States may supplement their automated systems with manually-produced ATP cards or other issuance authorizations at the local level. Such activity typically involves actions on new applications, returns, replacements, and changes, etc. The recommendation is not to design a system to preclude these types of supplementary activity which are outside the system.

Rather, the design recommendation is to simply have the capability to sum and report on the activity within the system. These totals will then have to be adjusted manually, to account for estimations of the volume of activity occurring outside the system, to arrive at the FNS-388 estimate of the current month totals. It at least provides a factual base for current month adjustments for this manual activity, rather than having to make that adjustment to an estimated base number.

States which are readily producing FNS-388 estimates that are within established accuracy standards may not need to implement this recommendation. Those states having difficulty meeting the accuracy standards may wish to consider implementing the recommendation, or requesting FNS assistance.

Form FNS-256 Reporting Requirement

Because the Department will be receiving monthly estimates of State participation, it will no longer need actual participation data for each project each month. The estimates on the FNS-388 will be sufficiently accurate for reports to Congress and the public. However, the Department does need occasional actual participation data by project areas for use in various trend projections, other studies, and to monitor periodically the accuracy of the FNS-388.

The Department, therefore, proposes that State agencies submit an FNS-256 report on a quarterly, rather than a monthly, basis. Starting in FY 1981, FNS-256 reports by project area would be due for the months of October, January, April, and July. However, FNS is not prepared to eliminate monthly participation data until assured of the accuracy of the estimates provided on the new FNS-388 report.

Therefore, a State agency must continue to submit actual monthly project level participation on the FNS-256 for the balance of FY 1980. FNS will compare these reports with the FNS-388 for the corresponding month. If the FNS-388 reports meets all accuracy standards set by FNS consistently for the months of June, July, and August the FNS Regional Office will approve future project area FNS-256 reporting on a quarterly basis starting no earlier than October 1980. Failure to meet the accuracy standards for the FNS-388 will necessitate continuance of the monthly project area FNS-256 report until the accuracy standards are met for three consecutive months. It is essential for this determination that States submit FNS-256 and FNS-250 reports on a timely basis. Late or incomplete reports may cause a State to fail the accuracy standards and delay Regional Office approval for the reduced FNS-256 reporting system. States may, if they choose, continue to receive participation data from their project areas on a monthly basis for their internal use. (A copy of a revised FNS-256 report is attached for comment).

Implementation

FNS proposes that all States will submit the Form FNS-388 for the month following the effective date of the final regulations. State estimation procedures would have to be submitted to the Regional Office prior to submitting the first report. State agencies already participating as pilot States need not resubmit their procedures.

Therefore, it is proposed that 7 CFR Part 274 by amended by revising § 274.8(a)(6) to read as follows:

PART 274—ISSUANCE AND USE OF COUPONS

§ 274.8 State agency reporting and destruction of unusable coupons.

(a) *State agency reporting.* * * *

(6) The State agency shall report on coupon issuance and participation on the Food Stamp Program as follows:

(i) The State agency shall mail the FNS–388, State Coupon Issuance and Participation Estimates to the FNS Regional Office by no later than the 19th of each month. The FNS–388 shall contain statewide estimates of the dollar value of coupons issued, and estimates of the number of households and persons who have participated based on State estimating procedures evaluated by FNS as required in paragraph (a)(6)(ii) of this section. The FNS–388 shall contain estimates for the current month and revised estimates for the preceding month and shall be signed by a designated State agency official. The State agency shall telephone the FNS–388 data to the appropriate Regional Office on the 19th of each month, prior to mailing the report to that office. When the 19th falls on a weekend or holiday the FNS–388 data shall be reported by telephone and mailed on the first working day after the 19th.

(ii) The State agency shall submit the estimation procedures to be used in producing the FNS–388 to the FNS Regional Office for review and comment. The estimation procedures shall be documented by the State agency in a manner prescribed by FNS. FNS shall monitor on a monthly basis the accuracy of the estimated dollar value of coupons issued as reported on the FNS–388 against the total dollar value of coupons issued as reported by the State agency for all issuance agents on the Forms FNS–250 for the corresponding month. FNS shall monitor periodically the accuracy of the estimated numbers of households and persons participating as reported on the FNS–388 against the actual total participation for all project areas as reported on the FNS–256 for the corresponding month. Current month's Estimates shall be within ± 4% and previous month's estimates shall be with ± 2% of actual amounts. If the degree of accuracy falls outside of these tolerances. FNS shall notify the State agency and assist the State agency in revising its estimation procedures to improve the degree of accuracy in no event shall the failure to meet these tolerance result in an administrative or fiscal sanction against the State agency FNS may require resumption of monthly project area reporting on the FNS–256 by withdrawing its approval in paragraph (a)(6)(iii) of this section if the State agency refuses to improve its estimating procedures or fails to meet the tolerances for bonus dollars for 3 consecutive months.

(iii) The State agency shall mail to the FNS Regional Office the Form FNS–256, Project Area Participation and Coupon Issuance, for each project area by the 45th day following the end of the report month. The FNS–256 shall contain each project's area's actual participation by the number of households and persons and the dollar value of coupons actually issued. The State agency shall submit an FNS–256 monthly for each project area until September 1980 or until approved by the FNS Regional Office to discontinue monthly reporting, whichever is later. If the State agency achieves the degree of accuracy on the FNS–388 specified in paragraph (a)(6)(ii) of this section for at least three consecutive months for "current" and "previous" months and for all three categories of bonus dollars, persons, and households, the FNS Regional Office shall notify the State agency that it may, starting in October 1980, discontinue the FNS–256 as a monthly report. Thereafter, the State agency shall submit the FNS–256 for the months of October, January, April, and July.

* * * * *

Note.—Form FNS–256 is being revised to incorporate the requirements of this amendment and will be forwarded to the Office of Management and Budget for approval in accordance with Federal Reports Act of 1942. In addition, Form FNS–388 is proposed and will be forwarded to the Office of Management and Budget for approval.

The forms are shown for information purposes and will not appear in the Code of Federal Regulations.

(91 Stat. 958 (7 U.S.C. 2011–2027))

(Catalog of Federal Domestic Assistance Programs No. 10.551 Food Stamps)

Dated: May 19, 1980.

Carol Tucker Foreman,

Assistant Secretary.

BILLING CODE 3410–30–M

OMB NO. _____

FORM FNS-256, PROJECT AREA PARTICIPATION
AND COUPON ISSUANCE
(FOOD STAMP PROGRAM)

(1) STATE: _____
(2) NAME OF PROJECT AREA: _____
(3) PROJECT CODE: _____
(4) REPORT MONTH AND YEAR: _____
(5) ☐ ORIGINAL SUBMISSION OR
_____ REVISION
(No.)

Due Date: Mail the original and one copy to the FNS Regional Office as soon as possible after the last day of the report month, but no later than 45 days following the last day.

INSTRUCTIONS ON COMPLETION OF THIS FORM ARE FOUND ON THE BACK OF THE LAST COPY.

(6) VALUE OF COUPONS ISSUED:
(In ATP States, include
all transacted ATP cards) $_____

(7) TOTAL PARTICIPATION:

a. Number of households: _____

b. Number of persons: _____

REMARKS:

(8) I CERTIFY THAT THIS REPORT IS CORRECT ACCORDING TO THE RECORDS OF THIS OFFICE.

DATE: _____

NAME OF AUTHORIZING OFFICIAL: _____

TITLE OF AUTHORIZING OFFICIAL: _____

Original - National Office
Copy 1 - Regional Office
Copy 2 - State Agency
Copy 3 - Project Area

FORM FNS-256
PROJECT AREA PARTICIPATION AND COUPON ISSUANCE
(FOOD STAMP PROGRAM)

Form FNS-256 shows participation and coupon issuance in the Food Stamp Program on a project area level for a one month period of time. State agencies submit the report quarterly for each project area in their State. The FNS-256 shall be submitted for the months of January, April, July, and October.

General Instructions

Data to be used in preparing this report must come from ATP cards transacted by households in the reporting project area, HIR cards used by the project area to provide issuance during the month, or mail issuance data if direct mail issuance is employed. In States using ATP issuance systems, the following procedures shall be used to determine how transacted ATPs shall be counted:

1. Altered, counterfeit, duplicate, expired and stolen ATPs shall be included.

2. Duplicate ATPs shall count as one transaction; however, the value of all coupons issued as a result if these cards' transaction shall be included in item 6.

3. Transacted, out-of-State ATP cards shall be counted as participation in the State agency and the value of coupons issued included in item 6.

4. ATPs issued after the 25th of the month shall be counted in the month transacted.

5. Out-of-project ATP cards shall be counted.

6. Disaster issuances shall be counted.

Item 1: Enter the name of the State.

Item 2: Enter the name of the project area.

Item 3: Enter the project code.

Item 4: Enter the report month and year, i.e., the month for which the data is collected. (January, April, July, October)

Item 5: Check if the report is an original submission or enter the number if it is a revision.

Item 6: Enter the total dollar value of coupons issued that month.

Item 7a: Enter the total number of households that participated in the Food Stamp Program in the project area during the report month.

Item 7b: Enter the total number of persons that participated in the project area during that month.

Item 8: Enter the date on which the report is submitted and the signature and title of the authorizing official.

FORM FNS - 388
STATE COUPON ISSUANCE
AND PARTICIPATION ESTIMATES

DATE: _____ (A)

STATE: _____ (B)

Instructions for completing this form are contained on the reverse of "Copy 1 - State Agency Copy".

	CURRENT MONTH	PREVIOUS MONTH
	Column A.	Column B
1. Month/Year	(C)	(D)
2. Estimated Coupon Issuance (Dollars)	(E)	(F)
3. Estimated Number of Participating People	(G)	(H)
4. Estimated Number of Participating Households	(I)	(J)

5. Remarks: (Optional) (K)

Due Dates: States telephone and mail this report to the regions no later than close of business on the nineteenth of the month.

SIGNED: _____ (L)

TITLE: _____ (M)

Original - Regional Office Copy
Copy 1 - State Agency Copy

FORM FNS-388
STATE COUPON ISSUANCE AND PARTICIPATION ESTIMATES
(FOOD STAMP PROGRAM)

Instructions

General: Form FNS-388 is a report of coupon issuance and participation in the Food Stamp Program. Each State agency completes and submits the report once a month. The report shows an estimate of statewide totals for the current month, and a revised estimate for the preceeding month.

All dollar and participation numbers should be provided to the nearest hundred.

Due Date: By the 19th of each month, phone data to the appropriate FNS Regional Office Financial Manager, and mail the original to the FNS Regional Office.

Entering Data: Each block of the Form FNS-388 should be completed in accordance with the following instructions:

Item (A): Show the date the form is completed.

Item (B): Show the State (name) for which the report is completed.

Item (C): Show the month and year of the current month (e.g., 1/80).

Item (D): Show the month and year of the preceeding month (e.g., 12/79).

Item (E): Show the dollar estimate of total coupon issuance for your State for the current month, developed in accordance with prescribed State estimating procedures provided to FNS.

Item (F): Show the revised dollar estimate of total coupon issuance for the preceeding month, using prescribed State procedures.

Item (G): Show the estimate of people participating in the current month.

Item (H): Show the revised estimate of the number of people that participated in the preceeding month.

Item (I): Show the estimated number of households participating in the current month.

Item (J): Show the revised estimate of the number of households that participated in the preceeding month.

Item (K): At State agency option, provide an explanation of any unusual circumstances that have caused issuance and/or participation data to change significantly since the last FNS-388 report.

Item (L): The FNS-388 should be signed by the person responsible for completing the report.

Item (M): Show the title of the person completing the report.

[FR Doc. 80-16033 Filed 5-23-80; 8:45 am]
BILLING CODE 3410-30-C

Food Safety and Quality Service

7 CFR Part 2856

Voluntary Grading of Shell Eggs; Advance Notice of Proposed Rulemaking

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Quality Service announces the completion and availability from the Department of Agriculture, upon request, of a document, "Advance Notice of Proposed Rulemaking," setting forth possible changes in its Regulations Governing the Grading of Shell Eggs and United States Standards, Grades, and Weight Classes for Shell Eggs (7 CFR Part 2856). Prior to making a final proposal, the Agency is seeking public comments on the material contained in the "Advanced Notice of Proposed Rulemaking."

DATE: Comments must be received on or before August 25, 1980.

ADDRESS: Request for copies of the document, "Advance Notice of Proposed Rulemaking," to: Ashley R. Gulich, Chief, Poultry Standardization Branch, Poultry and Dairy Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250. (Copies provided without charge.)

Written comments on the "Advance Notice of Proposed Rulemaking" to: Executive Secretariat, ATTN: Annie Johnson, Food Safety and Quality Service, U.S. Department of Agriculture, Room 2637, South Agriculture Building, Washington, DC 20250. (For additional information on comments, see supplementary information.)

FOR FURTHER INFORMATION CONTACT: Ashely R. Gulich, Chief, Poultry Standardization Branch, Poultry and Dairy Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–3506.

SUPPLEMENTARY INFORMATION:

Comments

Interested parties are invited to submit comments and information regarding the "Advance Notice of Proposed Rulemaking." Written comments must be sent in duplicate to the Executive Secretariat. Comments should bear reference to the date and page number of this issue of the Federal Register. All comments submitted will be made available for public inspection in the office of the Executive Secretariat during regular business hours. (7 CFR 1.27(b))

The Department needs all available information on the proposed changes, favorable or otherwise, including potential economic impact. To be of maximum value to the Department, the comments should be as specific as possible and contain supporting data. For example, being for or opposed to a change is of little value unless the reasons are given and the impact is indicated.

Background

The proposed changes are prompted by an evaluation by the Food Safety and Quality Service of the effectiveness of its shell egg standards in today's marketplace. "Checks" are an unavoidable problem in the marketing of eggs because eggs cannot be assembled, graded, packed, transported, and merchandized without some breakage. The "checked" eggs resulting from these operations and the percentage of such eggs permitted pose a problem in meeting the present standards. The Agency believes that changes could be made which would reflect present-day technology in the production, processing, and marketing of eggs; simplify the grading system by reducing the number of grades; and enhance the uniform application of grade standards.

The purpose of this "Notice of Availability" is to inform interested parties of the availability of the "Advance Notice of Proposed Rulemaking" and to invite comment. Briefly, the changes under consideration would:

1. Increase the tolerance for Checks in U.S. Consumer Grade A eggs at destination.
2. Increase the percentage of A quality or better eggs required in U.S. Consumer Grade A at origin and destination.
3. Eliminate the C quality classification.
4. Eliminate U.S. Grade AA and Fresh Fancy Quality, the U.S. Procurement Grades, and the three lower U.S. Wholesale Grades. (The proposed change to eliminate U.S. Grade AA is not associated with the Department's current study to determine consumer perceptions of USDA grades and the food grading program.)

Other minor changes, some primarily of a housekeeping nature, are also under consideration.

Distribution of the "Advance Notice of Proposed Rulemaking" is being made to State Departments of Agriculture, shell egg plants using USDA's voluntary grading service, poultry trade associations, other interested parties who are listed to receive changes in the shell egg regulations, and consumer organizations.

Done at Washington, D.C., on May 20, 1980.

Donald L. Houston,

Administrator, Food Safety and Quality Service.

[FR Doc. 80-16017 Filed 5-23-80; 8:45 am]

BILLING CODE 3410-DM-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

[Docket No. PRM-2-7]

Wells Eddleman; Notice of Denial of Petition for Rulemaking

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is hereby denying a petition for rulemaking (PRM-2-7) submitted by Mr. Wells Eddleman. The petitioner had requested the Commission to amend its regulations to provide that a person or corporation newly arrived in the vicinity of a nuclear power plant, or an organization formed after the deadline for intervention, be deemed to have shown good cause for the late filing of a petition for leave to intervene.

FOR FURTHER INFORMATION CONTACT: Bruce A. Berson, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: 301–492–7678.

SUPPLEMENTARY INFORMATION: The petition for rulemaking (PRM-2-7) submitted by Mr. Wells Eddleman, Rt. 1, Box 183, Durham, North Carolina requested the Nuclear Regulatory Commission to amend its regulations, "Rules of Practice for Domestic Licensing Proceedings," 10 CFR Part 2, 2.714(a)(1)(i) relating to what constitutes good cause for a late filed petition to intervene. The suggested amendment would, in petitioner's view, explicitly recognize and permit a person or corporation newly arrived in the vicinity of a nuclear power plant or an organization formed after the deadline for intervention to petition with good cause for the late filing to intervene. While petitioner asserts that it is his belief that "good cause" already includes the fact of recent arrival or formation of an organization, the amendment is offered to make this explicit and to possibly gain for this petitioner standing in a proceeding in which his late filed petition to intervene

was denied for failure to show good cause.

Specifically, the petitioner requests that the Commission amend § 2.714 of 10 CFR 2 as follows, replacing section (a)(1)(i) with this wording: (i) Good cause if any, for failure to file on time. Good cause shall include acquiring an interest in the proceeding, particularly by exercising Constitutional rights (e.g., free movement), after the deadline for filing, provided such acquisition of interest was not primarily intended to give cause for leave to intervene. Further, any organization formed after the deadline for intervention but without the express intent to circumvent the filing deadline by so organizing, and any corporate person moving into the vicinity of a nuclear power plant a significant office, factory or moveable property shall also be considered as having good cause for nontimely filing.

A notice of filing of the petition requesting comments by April 9, 1979 was published in the Federal Register on February 8, 1979 (44 FR 8043–44). Twenty-one comments were received. Six comments, of which five were from private citizens including the petitioner himself and one from an environmental group, were in support of the petition. Fifteen comments, of which nine were from private citizens, three from utilities, two from law firms, and one from an officer of an academic institution, opposed the proposed rule change. Those in favor of the proposed rule change generally believed that their rights as citizens were abridged by not being permitted to participate in a nuclear licensing proceeding—no matter how late their entry. Those opposed to the proposed rule change argued that it was unnecessary (that the existing rules already permit late intervention upon a proper balancing of factors), potentially disruptive to licensing proceedings, likely to delay or obstruct licensing without corresponding benefit to public, and contrary to proper adjudicatory process. The petition and comments are available for public inspection at the NRC Public Document Room at 1717 H Street NW., Washington, D.C.

Since its inception, the Commission has recognized the need for and desirability of effective public participation in the nuclear power plant licensing process. At the same time, the Commission is concerned with and responsible for efficiency in the Commission's adjudicatory process. In that connection, the Commission believes that unnecessary or inappropriate delays should be avoided whenever possible in the conduct of public hearings.

The Licensing Boards and Appeal Boards are well aware of their duty to maintain the integrity of the Commission's regulations as to the efficient conduct of its proceedings while carrying out the Commission's expressed interest and objective of affording public participation in the licensing process. The Commission continues to believe that the initial decision whether to grant or deny late intervention is most properly made by the presiding officer or licensing board designated to rule on the petition and that the existing factors set forth in 10 CFR § 2.714 are sufficient guidance in arriving at that decision. When a Board rules on a late petition for intervention and applies these factors, it is making a determination which is heavily dependent on the facts and circumstances of the particular case. The following factors are to be balanced in reaching a decision whether a late filed petition to intervene should be granted: (1) good cause, if any, for failure to file on time; (2) the availability of other means whereby the petitioner's interest will be protected; (3) the extent to which petitioner's participation may reasonably be expected to assist in developing a sound record; (4) the extent to which petitioner's interest will be represented by existing parties; and (5) the extent to which the petitioner's participation will broaden the issues or delay the proceeding. In addition, the following factors are also to be considered: (1) the nature of petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest.

It is well established that the adjudicatory process, whether before the courts or administrative tribunals, must be conducted in a manner to assure the integrity and orderly dispatch of the proceeding, to avoid undue delay or prejudice to the rights of existing parties and to permit finality in the process. The consequences of the proposed rule change—which would permit late intervention in an NRC proceeding to a person or corporation simply on the basis of recent arrival in the vicinity of a nuclear power plant site, or to an organization on the basis of its recent formation—would be decisions whose certainty and finality would be open to question and an adjudicatory process which could not be conducted in an orderly and expeditious manner.

The Commission has therefore concluded that the "good cause" requirement of 10 CFR § 2.714(a)(1)(i) should not be amended to explicitly encompass the situation of a newly arrived resident or newly formed organization in the vicinity of a nuclear power plant. This, by itself, does not, in the Commission's view, automatically establish good cause to permit late intervention. Late intervention by a newly arrived person or newly formed organization may be granted, however, upon full consideration of the factors set forth in 10 CFR § 2.714.

In his petition, petitioner also states that: "I personally have an interest in this proceeding because I unwittingly moved close to a nuclear plant site in 1977 (12 August), and wish to be afforded the same opportunity to petition to intervene as anyone who was living in the area when the plant was proposed or its initial hearings held. I do not ask any suspension of any proceedings. I do request that should this proposed rule be adopted in whole or in part it be applied to my case retroactively to this date or to the date of filing of any petitions to intervene which makes a point of late intervention by exercise of Constitutional rights etc. as specified in my proposed rule, including the right to a rehearing based on this proposed rule if and when it is made part of 10 CFR 2."

The proceeding to which petitioner refers is *Carolina Power and Light Co.*, Shearon Harris Nuclear Power Plant, Units 1, 2, 3, and 4, Dkt. Nos. 50–400, 401, 402, and 403. Our determination on the proposed rule renders moot petitioner's request for retroactivity.

In view of the foregoing, the Commission has denied the petition for rule making filed by Wells Eddleman on January 4, 1979. A copy of the Commission's letter of denial is available for public inspection at the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

Dated at Washington, D.C., this 20th day of May, 1980.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 80-15950 Filed 5-23-80; 8:45 am]

BILLING CODE 7590-01-M

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Ch. VII

Premiums, Finders Fees and the Payment of Dividends in Merchandise

AGENCY: National Credit Union Administration.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Depository Institutions Deregulation Commttee ("Committee") has proposed to adopt a rule concerning the offering of premiums or gifts by banks and savings and loan associations. The National Credit Union Administration is requesting comments on whether, and to what extent, the Committee's proposal should be made applicable to Federal credit unions. Under the Committee's proposed rule, if made applicable to Federal credit unions, the giving to a member of a premium or gift (whether in the form of cash or merchandise) by a Federal credit union associated directly with the purchase of shares would be prohibited. In addition, finders fees paid to third parties would be regarded as the payment of dividends to the member and would be required to be paid only in cash. The NCUA Board also is considering adoption of a proposed rule that would require that all dividends paid on shares be paid only in the form of cash or a credit to a share or share certificate account. This rule would also codify present NCUA policy of prohibiting the prepayment of dividends in the form of merchandise.

DATES: Comments must be received by June 23, 1980.

ADDRESS: Interested parties are invited to submit written data, views or comments regarding the proposed rules to Robert S. Monheit, Regulatory Development Coordinator, National Credit Union Administration, 1776 G Street, N.W., Washington, DC 20456.

FOR FURTHER INFORMATION CONTACT: James J. Engel, Assistant General Counsel or Todd A. Okun, Senior Attorney (both at 202–357–1030), Office of General Counsel, National Credit Union Administration.

SUPPLEMENTARY INFORMATION: Under the current policies of this Administration (and the other Federal financial regulatory agencies), a premium given to a member upon the opening of a new account or an addition to an existing account is not regarded as the payment of a dividend if the cost of the premium (excluding shipping and packaging costs) does not exceed $5 for share purchases of less than $5,000 and $10 for share purchases of $5,000 or more, and the premium is not given on a recurring basis to the same individual. (Administrator's Letter, July, 1978)

The following is the Committee's description of the pertinent issues about which comments are solicited concerning their applicability to Federal credit unions:

"In recent months, the attention of the Federal financial institutions regulatory agencies has been directed to possible circumvention of interest rate limitation through the use of premiums to induce deposits and finders fees paid to a person who introduces a depositor to an institution. Such programs require a substantial amount of examiner time investigating complaints and reviewing compliance. The current premium rule was adopted by the agencies in 1970 in order to establish what constituted a *de minimis* gift that would not be regarded as the payment of interest. It was intended that the rule would clarify this matter and reduce time spent by the agencies in reviewing individual programs. However, in practice the rule is difficult to enforce because it can be circumvented by attributing an inflated portion of the total cost of the premium to shipping and packaging, rather than to the direct wholesale cost of the premium. In addition, some institutions may have been billed at an average cost for a group of different items, thus enabling the institutions to provide premium that would otherwise exceed the limitations. Consequently, the existing rule does not appear to have served its original purpose.

"Finders fees, whether in the form of cash or merchandise, are fees paid to a person who introduces a depositor to an institution. The finders fee is typically related to the size of the deposit received by the institution. Under the current rules of the FHLBB, the cost of any premiums given to a depositor and finders fees given to a third party are regarded as the payment of interest if in excess of $5 for deposits of less than $5,000 and $10 for deposits of $5,000 or more. The rules of the FDIC and Federal Reserve do not restrict the use of finders fees paid to third parties. However, if any portion of the fee is passed on to the depositor or a member of the depositor's household, it is regarded as additional interest on the deposit.

"Recently, banks have increased use of finders fees to attract deposits. There are indications that finders fees are being employed to avoid current premium limitations and that some or all of such fees may go to the depositor. To the extent that such a practice occurs, it results in a circumvention of interest rate ceilings.

"In view of these considerations, the Committee is considering adoption of a rule that would prohibit the giving to a depositor of a premium or gift (whether in the form of cash or merchandise) upon the opening of a new account or an addition to an existing account. The Committee also is considering adoption of a rule that would require that all finders fees be paid only in cash and that would regard such fees as the payment of interest to the depositor for the purpose of deposit rate ceilings. With reference to finders fees, comment specifically is requested on the extent to which such fees are passed on to or shared with depositors and procedures utilized to ensure that such fees are not passed on to depositors.

"Comment also is requested on alternatives to prohibiting the use of premium.

"The Committee also is considering adoption of a rule that would require that all interest paid on a deposit be paid only in the form of cash or a credit to a deposit account. The Committee believes that this rule would benefit consumers by making the amount of interest paid on a deposit explicit, thus facilitating comparisions by depositors and reducing potential customer confusion as to the actual return earned on a deposit. This rule would have the effect of eliminating programs, currently authorized under FDIC and Federal Reserve rules, in which interest is prepaid in the form of merchandise. Comment also is requested on whether the prepayment of interest in cash should be prohibited."

All comments and information on these proposals should be submitted to Robert S. Monheit, Regulatory Development Coordinator, National Credit Union Administration, 1776 G Street, N.W., Washington, DC 20456, to be received by June 23, 1980. Material submitted will be made available for inspection and copying upon request except as provided in section 720 of NCUA Rules and Regulations (12 CFR § 720).

Rosemary Brady,

Secretary to the Board.

May 20, 1980.

[FR Doc. 80-15831 Filed 5-23-80; 8:45 am]

BILLING CODE 7535-01-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 590

[No. 80-287]

Mobile Home Loan Consumer Protection Provisions

Correction

In FR Doc. 80–14577, appearing at page 31122 in the issue for Monday, May 12, 1980, on page 31123, in the third column, in § 590.4, between paragraph (a) and paragraph (i) insert the following:

(1) *Prepayment.* A "prepayment" occurs upon—

BILLING CODE 1505-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 80-WE-6]

Proposed Alteration of Transition Area, Reno. Nev.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rule making.

SUMMARY: This notice proposes to alter a portion of the transition area at Reno, Nevada, so as to provide controlled airspace for the increased volume of air traffic using routes east and southeast of South Lake Tahoe.

DATE: Comments must be received on or before June 26, 1980.

ADDRESSES: Send comments on the proposal in triplicate to Director, Federal Aviation Administration, Attn: Chief, Airspace and Procedures Branch, AWE-530, 15000 Aviation Boulevard, Lawndale, California 90261. A public docket will be available for examination in the Office of the Regional Counsel, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261. Telephone (213) 536-6270.

FOR FURTHER INFORMATION CONTACT: Thomas W. Binczak, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, Telephone: (213) 536-6182.

Comments Invited

Interested persons may participate in the proposed rule making by submitting such written data, views, or arguments as they may desire. Communications should identify the Airspace Docket Number and be submitted in triplicate to the Chief, Airspace and Procedures Branch, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261. All communications received on or before June 26, 1980, will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received. All comments received will be available both before and after the closing date for comments in the Rules Docket for examination by interested persons.

Availability of NPRM

Any person may obtain a copy of this notice of proposed rule making (NPRM) by submitting a request to the Federal Aviation Administration, Chief, Airspace and Procedures Branch, AWE-530, 15000 Aviation Boulevard, Lawndale, California, 90261, or by calling (213) 536-6180. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11-2 which describes the application procedures.

Drafting Information

The principal authors of this document are Thomas W. Binczak, Air Traffic Division and DeWitte T. Lawson, Jr., Esquire, Regional Counsel, Western Region.

The Proposal

The FAA is considering an amendment to Subpart G or Part 71 of the Federal Aviation Regulations (14 CFR Part 71) that would alter the Reno, Nevada transition area. This action will provide controlled airspace protection for IFR operations east and southeast of South Lake Tahoe.

The Proposed Amendment

Accordingly, the Federal Aviation Administration proposes to amend Subpart G, § 71.181 (45 FR 445) of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by adding the following:

§ 71.181 Reno, Nevada [Amended]

Following "* * * longitude 119°00'00" W.,* * * " add "that airspace extending upward from 12,300 feet MSL within 10 miles east of the Reno, Nevada VORTAC 173° radial and westerly to the east edge of V-165 extending from the 45 mile radius of the Reno VORTAC to the north edge of V-244; * * *."

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.65)

"Note.—The FAA has determined that this document involves a proposed regulation which is not significant under Executive Order 12044, as implemented by DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). Since this regulatory action involves an established body of technical requirements for which frequent and routine amendments are necessary to keep them operationally current and promote safe flight operations, the anticipated impact is so minimal that this action does not warrant preparation of a regulatory evaluation and a comment period of less than 45 days is appropriate.

Issued in Los Angeles, California on May 14, 1980.

W. R. Frehse,

Acting Director, Western Region.

[FR Doc. 80-15967 Filed 5-23-80 8:45 am]

BILLING CODE 4910-13-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1512

Proposed Amendments to Bicycle Safety Requirements: Retroreflective Rims

Correction

In FR Doc. 80-15195, published at page 32705, on Monday, May 19, 1980, on page 32706, in the first column, under Dates, the second sentence should be corrected to remove the date and read as follows: "The amendments are proposed to become effective 30 days after their publication in final form in the Federal Register."

BILLING CODE 1505-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 270

[Docket No. RM80-52]

Advance Payments Under the Natural Gas Policy Act of 1978; Correction

May 20, 1980.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Erratum notice.

SUMMARY: This notice contains a correction of the Notice of Proposed Rulemaking issued in Docket No. RM80-52 on April 23, 1980.

FOR FURTHER INFORMATION CONTACT: Jeffrey Fink, Office of the General Counsel, Federal Energy Regulatory Commission, Room 8111, 825 North Capitol Street NE., Washington, D.C. 20426, (202) 357-9460.

SUPPLEMENTARY INFORMATION: In the Federal Energy Regulatory Commission's Notice of Proposed Rulemaking issued on April 23, 1980, entitled Advance Payments Under the Natural Gas Policy Act of 1978 (45 FR 28345, April 29, 1980) the section number

of the proposed rule should be corrected to read "§ 270.208."

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-15973 Filed 5-23-80; 8:45 am]

BILLING CODE 6450-85-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 331

[Docket No. 79N-0433]

Antacid Drug Products for Over-The-Counter Human Use; Proposed Amendment of a Monograph

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the administrative procedures by which persons might request and be granted a modification of the in vitro test for over-the-counter (OTC) antacid drug products. This action is taken to make these procedures conform to the agency's current administrative regulations and to clarify the procedure for submitting such a request.

DATES: Comments by July 28, 1980.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD—510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 4, 1974 (39 FR 19862), FDA issued the final order for OTC antacid drug products generally recognized as safe and effective and not misbranded (21 CFR Part 331). This order was issued under § 330.10 of the OTC drug review procedures (21 CFR 330.10) promulgated in the Federal Register of May 11, 1972 (37 FR 9464) and was based on the conclusions and recommendations of the Advisory Review Panel on OTC Antacid Drug Products.

Section 331.29 (21 CFR 331.29) of the antacid monograph contains provisions for seeking a modification of the in vitro testing procedures set forth in Subpart C of Part 331 (21 CFR Part 331). The regulation currently requires that any proposed modifications and the data to support them be submitted to the Assistant Director for Implementation, OTC Drug Products Evaluation Staff, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, for approval before use. Because of a reorganization within the Bureau of Drugs since this final order was published, there is no such position at the present time. Also, the current regulation does not explain how requests for test modifications will be processed by the agency.

It is the purpose of this proposed amendment to indicate that the request for, and data in support of, proposed modifications of the in vitro testing procedures should be submitted to the office of the Hearing Clerk in the form of a citizen petition under the procedures established in the agency's general administrative regulations § 10.30 (21 CFR 10.30). Consistent with the procedures under § 10.30, the agency will notify the petitioner in writing whether the petition is granted or denied. It is the intention of FDA that the authority to grant or deny petitions seeking modification of the vitro testing procedures in 21 CFR Part 331 be redelegated from the Commissioner of Food and Drugs to the Director or Deputy Director of the Division of Over-The-Counter Drug Evaluation. Therefore, final regulations issued under this proposal will include a redelegation of authority under Subpart B of Part 5 (21 CFR Part 5).

The proposed procedure in which any request for a test modification is to be submitted as a petition to the office of the Hearing Clerk is in keeping with the public nature of the OTC drug review. Similarly, any decisions regarding such a petition will be placed on public display.

The Food and Drug Administration has determined that under 21 CFR 25.24(b)(12) (proposed in the Federal Register of December 11, 1979; 44 FR 71742) this proposed action is of a type that does not have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371) and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1)), it is proposed that Part 331 be amended by revising § 331.29, to read as follows:

§ 331.29 Test modifications.

The formulation or mode of administration of certain products may require modification of this in vitro test. Any proposed modification and the data to support it shall be submitted as a petition under the rules established in § 10.30 of this chapter. All information submitted will be subject to the disclosure rules in Part 20 of this chapter.

Interested persons may, on or before July 28, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: May 20, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-15979 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 80-059]

Drawbridge Operation Regulations; Barnegat Bay, N.J.

AGENCY: Coast Guard, DOT.

ACTION: Proposed rule.

SUMMARY: At the request of the New Jersey Department of Transportation, the Coast Guard will consider changing the regulations governing the operation of the Route 37 drawbridge across Barnegat Bay, mile 14.1 of the Intracoastal Waterway of New Jersey, at Island Heights, New Jersey to allow the draw to remain closed to marine traffic from 11 p.m. to 7 a.m. during the months of December, January, February

and March. The New Jersey Department of Transportation has made this request due to infrequent openings during the aforementioned period. If the Department's request is granted, it will be relieved of the expense of providing full-time drawtenders during these hours while still providing for the reasonable needs of navigation.

DATE: Comments must be received on or before July 1, 1980.

ADDRESS: Comments should be submitted to and are available for examination during normal business hours at the office of the Commander(oan-br), Third Coast Guard District, Bldg. 135A, Governors Island, N.Y. 10004 (212–668–7165).

FOR FURTHER INFORMATION CONTACT: William C. Heming, Bridge Administrator, Aids to Navigation Branch, Third Coast Guard District, Bldg., 135A, Governors Island, N.Y. 10004 (212–668–7165).

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting views, data, or arguments. Persons submitting comments should include their names and addresses, identify the bridge, and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped self-addressed envelope or postcard. The Commander, Third Coast Guard District, will evaluate all communications and determine a final course of action on this proposal. The proposed regulations may be changed in light of comments received.

DRAFTING INFORMATION: The principal persons involved in drafting this rule are: Richard A. Gomez, Project Manager, and Lieutenant Bruce H. Tobey, Project Attorney, Third Coast Guard District.

Discussion of the Proposed Regulations

The Route 37 drawbridge provides access for vehicular traffic over Barnegat Bay between Seaside Heights and Island Heights. An investigation conducted by the Commander(oan-br), Third Coast Guard District revealed that there were only two openings of the draw between the hours of 11 p.m. and 7 a.m. during the months of December, January, February and March of 1977, 1978 and 1979. Present regulations require that the draw shall open on signal except from 10 a.m. to 2 p.m. on Saturdays, Sundays, and holidays from memorial Day through Labor Day, when it need open only on the hour and half hour.

In consideration of the foregoing, it is porposed that Part 117 of Title 33 of the Code of Federal Regulations be amended by revising § 117.220(p) to read as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

§117.220 New Jersey Intracoastal Waterway and tributaries; bridges.

* * * * *

(p) Route 37 Bridge across Barnegat Bay. The draw shall open on signal except:

(1) From 11 p.m. to 7 a.m. during the months of December, January, February and March the draw need not open to navigation; and

(2) From 10 a.m. to 2 p.m. Saturdays, Sundays, and holidays, from Memorial Day through Labor Day the draw need only open on the hour and half hour, except that it shall open at any time for the passage of vessels with tows during such periods.

* * * * *

(33 U.S.C. 499, 49 U.S.C. 1655(g)(2); 49 CFR 1.46(c)(5); 33 CFR 1.05–1(g)(3))

R. I. Price,

Vice Admiral, U.S. Coast Guard, Commander, Third Coast Guard District.

[FR Doc. 80–16029 Filed 5–23–80; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 117

[CGD 80–060]

Drawbridge Operation Regulations; Cheesequake Creek, N.J.

AGENCY: Coast Guard, DOT.

ACTION: Proposed rule.

SUMMARY: At the request of the New Jersey Department of Transportation, the Coast Guard will consider changing the regulations governing the operation of the Route 35 drawbridge across Cheesequake Creek, mile 0.0, at Morgan, New Jersey, to allow the draw to remain closed to marine traffic from 11 p.m. to 7 a.m. daily during the months of December, January, February, and March. The New Jersey Department of Transportation has made this request because of infrequent openings during the aforementioned period. If the Department's request is granted, it will be relieved of the expense of providing full-time drawtenders during these periods while still providing for the reasonable needs of navigation.

DATES: Comments must be received on or before July 1, 1980.

ADDRESSES: Comments should be submitted to and are available for examination during normal business hours at the office of the Commander (oan-br), Third Coast Guard District, Bldg. 135A, Governors Island, N.Y. 10004 (212–668–7165).

FOR FURTHER INFORMATION CONTACT: William C. Heming, Bridge Administrator, Aids to Navigation Branch, Third Coast Guard District, Bldg. 135A, Governors Island, N.Y. 10004 (212–668–7165).

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting views, data or arguments. Persons submitting comments should include their names and addresses, identify the bridge and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped self-addressed envelope or postcard. The Commander, Third Coast Guard District, will evaluate all communications and determine a final course of action on this proposal. The proposed regulations may be changed in light of comments received.

DRAFTING INFORMATION: The principal persons involved in drafting this rule are: Richard A. Gomez, Project Manager, and Lieutenant Bruce H. Tobey, Project Attorney, Third Coast Guard District.

Discussion of the Proposed Regulations

The Route 35 drawbridge provides access for vehicular traffic over Cheesequake Creek between Lawrence Harbor and South Amboy. An investigation conducted by the Commander(oan-br), Third Coast Guard District, revealed that there were no openings of the draw between the hours of 11 p.m. and 7 a.m. during the months of December, January, February, and March of 1977, 1978, and 1979. Present regulations require that the draw need only open on the hour from May 15 to October 15 between 7 a.m. and 7 p.m.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulation be amended by revising § 117.215(j)(4) to read as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

§ 117.215 Navigable streams flowing into Raritan Bay (except Raritan River and Arthur Kill), the Shrewsbury River and its tributaries and all inlets on the Atlantic Ocean including their tributaries and canals between Sandy Hook and Bay Head, N.J.; bridges.

* * * * *

(j) The general regulations contained in paragraphs (a) to (g) inclusive, of this section shall apply to all bridges except

as modified by the special regulations contained in this paragraph.

* * * * *

(4) Route 35 drawbridge across Cheesequake Creek at Morgan, South Amboy, N.J. The draw shall open on signal except:

(i) From 11 p.m. to 7 a.m. daily during the months of December, January, February, and March where the draw need not open to navigation; and

(ii) From 7 a.m. to 7 p.m. from May 15 through October 15 the draw need only open on the hour.

* * * * *

(33 U.S.C. 499, 49 U.S.C. 1655(g)(2); 49 CFR 1.46(c)(5); 33 CFR 1.05-1(g)(3))

R. I. Price,

Vice Admiral, U. S. Coast Guard Commander, Third Coast Guard District.

[FR Doc. 80-16030 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 117

[CGD 80-058]

Drawbridge Operation Regulations; Manasquan River, N.J.

AGENCY: Coast Guard, DOT.

ACTION: Proposed rule.

SUMMARY: At the request of the New Jersey Department of Transportation, the Coast Guard will consider changing the regulations governing the operation of the Route 70 drawbridge across the Manasquan River, mile 3.4 at Brielle, Monmouth County, New Jersey to allow the draw to remain closed to marine traffic daily from 11 p.m. to 7 a.m. The New Jersey Department of Transportation has made this request due to infrequent openings during these hours. If the Department's request is granted, it will be relieved of the expense of providing full-time drawtenders during these hours while still providing for the reasonable needs of navigation.

DATE: Comments must be received on or before July 1, 1980.

ADDRESS: Comments should be submitted to and are available for examination during normal business hours at the office of the Commander(oan-br), Third Coast Guard District, Bldg. 135A, Governors Island, New York, N.Y. 10004 (212-668-7165).

FOR FURTHER INFORMATION CONTACT: William C. Heming, Bridge Administrator, Aids to Navigation Branch, Third Coast Guard District, Bldg. 135A, Governors Island, N.Y. 10004 (212-668-7165).

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting views, data or arguments. Persons submitting comments should include their names and addresses, identify the bridge and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped self-addressed postcard or envelope. The Commander, Third Coast Guard District will evaluate all communications and determine a final course of action on this proposal. The proposed regulations may be changed in light of comments received.

DRAFTING INFORMATION: The principal persons involved in drafting this rule are: Richard A. Gomez, Project Manager, and Lieutenant Bruce H. Tobey, Project Attorney, Third Coast Guard District.

Discussion of the Proposed Regulations

The Route 70 drawbridge provides access from Point Pleasant north to Brielle, New Jersey for vehicular traffic. The number of openings during the hours of 11 p.m. to 7 a.m. decreased from twelve in 1977 to four in 1979. Present regulations require the draw to open on signal if at least 12 hours advance notice is given from December 1 to March 31.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations be amended by revising § 117.225(f)(6) to read as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

§ 117.225 Navigable waters in the State of New Jersey; bridges where constant attendance of draw tenders is not required.

* * * * *

(f) The bridges to which this section applies, and the regulations applicable in each case, are as follows:

* * * * *

(6) Route 70 Bridge across the Manasquan River at Brielle, Monmouth County, New Jersey. From 11 p.m. to 7 a.m. daily the draw need not open to navigation. At all other times the draw shall open on signal.

* * * * *

(33 U.S.C. 499, 49 U.S.C. 1655(g)(2); 49 CFR 1.46(c)(5); 33 CFR 1.05-1(g)(3))

R. I. Price,

Vice Admiral, U.S. Coast Guard, Commander, Third Coast Guard District.

[FR Doc. 80-16028 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-14-M

DEPARTMENT OF THE INTERIOR

Office of Hearings and Appeals

43 CFR Part 4

Department Hearings and Appeals Procedures

AGENCY: Office of Hearings and Appeals, Department of the Interior.

ACTION: Proposed rule.

SUMMARY: This Office proposes changes to its procedural regulations to comply with Exec. Order No. 12044 "Improving Government Regulations" (43 FR 12661 (March 24, 1978)). The purpose of the proposed revisions is to update, reduce, and simplify language and to delete those provisions which are no longer needed.

DATE: Comments must be received on or before July 28, 1980.

ADDRESS: Send comments to: Director, Office of Hearings and Appeals, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Sara Russell, Attorney Advisor, Hearings Division, Office of Hearings and Appeals, (703) 557-9200.

SUPPLEMENTARY INFORMATION: Exec. Order No. 12044 directs each executive agency to adopt procedures to improve existing and future regulations. Among other things, agencies are charged with reviewing and revising existing regulations to make them as simple and clear as possible and to eliminate those that are no longer necessary. To comply with the directive, this Office established a Rules Committee to review and revise in toto its procedural regulations. Although the work of the committee is ongoing, at this time we propose changes to the following subparts of 43 CFR Part 4: Subpart A: Language is to be updated, reduced, and simplified. No substantive changes are proposed.

Subpart B: The general rules now existing is Subpart B (there are very few) are being included, where needed, in the several subparts of 43 CFR Part 4 so that each subpart can stand alone. When this is done Subpart B will be deleted.

Subpart H: These rules will be deleted to comply with Exec. Order No. 12086, which transfers all functions under Exec. Order No. 11246, *as amended* by Exec. Order No. 11375, to the Department of Labor.

Subpart I: Language is to be updated. No substantive changes are proposed.

Subpart K: These rules will be deleted because the deadline for disenrollment

contest review (October 1, 1978) has passed (*see* 25 CFR 43h.15(h)).

The policy of the Department of the Interior is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions, or objections regarding the proposed amendments.

The principal author of the proposed revisions is Ms. Sara Russell, Attorney-Adviser, Hearings Division, Office of Hearings and Appeals, Department of the Interior.

Note.—The Department of the Interior has determined that this document is not a significant rule and does not require a regulatory analysis under Exec. Order No. 12044 and 43 CFR Part 14.

Dated: May 21, 1980.

Ruth R. Banks,

Director, Office of Hearings and Appeals.

1. It is proposed to revise Subpart A of Part 4 of Title 43 of the *Code of Federal Regulations* as follows:

Subpart A—General; Office of Hearings and Appeals

Sec.

Subpart A—General; Office of Hearings and Appeals

§ 4.1 Scope of authority.

The Office of Hearings and Appeals, headed by a Director, is an authorized representative of the Secretary for the purpose of hearing, considering, and determining, as fully and finally as might the Secretary, matters within the jurisdiction of the Department involving hearings, appeals, and other review functions of the Secretary (the organization of the Office of Hearings and Appeals and the authority delegated by the Secretary to the Director and other principal officials of the Office are set forth in Part 211, Chapter 13, of the Departmental Manual). Principal components of the Office include:

(a) A Hearings Division comprised of Administrative Law Judges who are authorized to conduct: (1) Hearings in cases required by law to be conducted pursuant to 5 U.S.C. 554 (1976); (2) hearings in Indian probate matters; and (3) hearings in other cases arising under statutes and regulations of the Department, including rulemaking hearings.

(b) Several Appeals Boards, described below, with administrative review jurisdiction.

(1) *Board of Contract Appeals.* The Board is authorized to exercise the authority granted to agency Boards of Contract Appeals by the Contract Disputes Act of 1978, Pub. L. 95–563, in deciding appeals from findings of fact, decisions, or failure to issue timely decisions by contracting officers of any bureau or office of the Department, wherever situated, or any field installation thereof, and order and conduct hearings as necessary with respect to cases under the Contract Disputes Act of 1978. The Board, as previously authorized by DM Release #2122 dated October 20, 1978, may continue to exercise the authority previously delegated to it with respect to those contract cases which are not subject to the provisions of the Contract Disputes Act of 1978. Special regulations applicable to proceedings before the Board are contained in Subpart C of this part.

(2) *Board of Indian Appeals.* The Board decides finally for the Department appeals to the head of the Department pertaining to: (i) Administrative actions of officials of the Bureau of Indian Affairs in cases involving determinations, findings, and orders protested as a violation of a right or privilege of the appellant, except enrollment and except the leasing of Indian land for oil and gas exploration and production under regulations in 25 CFR Part 2; and (ii) orders and decisions of Administrative Law Judges in Indian probate matters other than those involving estates of the Five Civilized Tribes of Indians and Osage Indian wills. The Board also decides other matters pertaining to Indians referred to it by the Director of the Office of Hearings and Appeals for exercise of the review authority of the Secretary. Special regulations applicable to proceedings before the Board are contained in Subpart D of this part.

(3) *Board of Land Appeals.* The Board decides finally for the Department appeals to the head of the Department from decisions by Departmental officials relating to the use and disposition of public lands and their resources and the use and disposition of mineral resources in certain acquired lands of the United States and in the submerged lands of the Outer Continental Shelf. Special procedures for hearings, appeals, and contests in public lands cases are contained in Subpart E of this part.

(4) *Board of Surface Mining and Reclamation Appeals.* The Board performs finally for the Department the appellate and other review functions of the Secretary under the Surface Mining Control and Reclamation Act of 1977, 30 U.S.C. 1201–1328 (Supp. I 1977).

(5) *Alaska Native Claims Appeal Board.* The Board considers and decides finally for the Department appeals to the head of the Department from findings of fact or decisions by Departmental officials in matters relating to land selection arising under the Alaska Native Claims Settlement Act, 43 U.S.C. 1601–1628 (1976), *as amended,* and any other statute dealing with Alaska Native claims except the Alaska Native Allotment Act, Act of May 17, 1906, 34 Stat. 197, *as amended.* The Board shall not consider: (i) Appeals relating to enrollment of Alaska Natives; (ii) appeals on rights granted and protected by section 14(c) of the Alaska Native Claims Settlement Act; (iii) appeals on easements brought by parties to agreements with the Department which set forth alternative procedures for easement appeals; and (iv) appeals relating to locations and entries under the mining and public land laws. With respect to appeals from Departmental decisions on village eligibility under section 11(b) of the Alaska Native Claims Settlement Act, decisions of the Board shall be submitted to the Secretary for approval before becoming final. Special regulations applicable to proceedings before the Board are contained in Subpart J of this part.

(6) *Ad Hoc Appeals Board.* Appeals to the head of the Department which do not lie within the appellate review jurisdiction of an established Appeals Board and which are not specifically excepted in the general delegation of authority to the Director, may be considered and ruled upon by the Director or by an Ad Hoc Appeals Board appointed by the Director to consider a particular appeal and to decide finally for the Department all questions of fact and law necessary for the complete adjudication of the issues. Special regulations applicable to proceedings in such cases are contained in Subpart G of this part.

§ 4.2 Rules governing hearings and appeals procedures.

Rules governing procedures before the various components of the Office of Hearings and Appeals are found in the relevant subparts of this part, in the substantive regulations and policies of the Department relating to the proceeding, and in the governing laws. Part 1 of this subtitle regulates practice before the Department of the Interior.

§ 4.3 Membership of appeals boards; decisions, functions of chief judges.

(a) The Appeals Boards consist of Administrative Judges and a Chief Administrative Judge. Except as provided by statute, the Director may serve as an ex officio member on any of the Boards, and alternate members may serve, when necessary, in place of or in addition to regular members. The Chief Administrative Judge of an Appeals Board may direct that an appeal be decided by a panel of any two Administrative Judges of the Board; but if they are unable to agree upon a decision, the Chief Administrative Judge may assign one or more additional Administrative Judges of the Board to consider the appeal. The concurrence of a majority of the Board Administrative Judges who consider an appeal shall be sufficient for a decision.

(b) Decisions of the Board must be in writing and signed by not less than a majority of the Administrative Judges who considered the appeal. The Director, being an ex officio member, may participate in the consideration of any appeal and sign the resulting decision.

(c) The Chief Administrative Judge of an Appeals Board shall be responsible for the internal management and administration of the Board, and is authorized to act on behalf of the Board in conducting correspondence and in carrying out such other duties as may be necessary in conducting the routine business of the Board.

§ 4.4 Representation before the Office of Hearings and Appeals.

(a) *Appearances generally.* Representation of parties in proceedings before the Office of Hearings and Appeals is governed by Part 1 of this subtitle, which regulates practice before the Department of the Interior.

(b) *Representation of the Government.* Department counsel designated by the Solicitor of the Department to represent agencies, bureaus, and offices of the Department of the Interior in proceedings before the Office of Hearings and Appeals, and Government counsel for other agencies, bureaus, or offices of the Federal Government involved in any proceeding before the Office of Hearings and Appeals, shall represent the Government agency in the same manner as a private advocate represents a client.

§ 4.5 Power of the Secretary and Director.

(a) *Secretary.* Nothing in this part shall be construed to deprive the Secretary of any power conferred upon him/her by law. The authority reserved to the Secretary includes, but is not limited to:

(1) The authority to take jurisdiction at any stage of any case before any employee or employees of the Department, including any Administrative Law Judge or Board of the Office, and to render the final decision in the matter after holding such hearing as may be required by law; and

(2) The authority to review any decision of any employee or employees of the Department, including any Administrative Law Judge or Board of the Office, or to direct any such employee or employees to reconsider a decision.

(b) *The Director.* Pursuant to delegated authority from the Secretary, the Director may assume jurisdiction of or review any case before any Board of the Office or direct reconsideration of any decision by any Board of the Office.

§ 4.6 Public records; locations of field offices.

Part 2 of this subtitle prescribes the rules governing availability of the public records of the Office of Hearings and Appeals. It includes a list of the field offices of the Office of Hearings and Appeals and their locations.

Subpart H—[Deleted]

2. It is proposed to delete Subpart H of Part 4 of Title 43 of the *Code of Federal Regulations* to comply with Exec. Order No. 12086, which transfers all functions under Exec. Order No. 11246, *as amended* by Exec. Order No. 11375, from the Department of the Interior to the Department of Labor.

3. It is proposed to revise Subpart I of Part 4 of Title 43 of the *Code of Federal Regulations* as follows:

Subpart I—Special Procedural Rules Applicable to Practice and Procedure for Hearings, Decisions, and Administrative Review Under Part 17 of This Title—Nondiscrimination in Federally Assisted Programs of the Department of the Interior—Effectuation of Title VI of the Civil Rights Act of 1964

General

Sec.
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Authority: 43 CFR 17.8 and 17.9 and 5 U.S.C. 301 (1976).

Subpart I—Special Procedural Rules Applicable to Practice and Procedure for Hearings, Decisions, and Administrative Review Under Part 17 of This Title—Nondiscrimination in Federally Assisted Programs of the Department of the Interior—Effectuation of Title VI of the Civil Rights Act of 1964.

Authority: 43 CFR 17.8 and 17.9 and 5 U.S.C. § 301 (1976).

Cross Reference: *See* 43 CFR 17.8 and 17.9 for additional rules applicable to hearings, decisions, and administrative review procedures under Part 17 of this title. *See also* Subpart A of this title for the organization, authority, and jurisdiction of the Office of Hearings and Appeals.

General

§ 4.800 Scope and construction of rules.

(a) The rules of procedures in this subpart supplement Part 17 of this title and are applicable to the practice and procedure for hearings, decisions, and administrative review conducted by the Department of the Interior, pursuant to Title VI of the Civil Rights Act of 1964 (section 602, 42 U.S.C. 2000d–1 (1976)) and Part 17 of this title concerning nondiscrimination in Federally-assisted programs in connection with which Federal financial assistance is extended under laws administered in whole or in part by the Department of the Interior.

(b) These regulations shall be liberally construed to secure the just, prompt, and inexpensive determination of all proceedings consistent with adequate consideration of the issues involved and full protection of the rights of all interested parties including the Government..

§ 4.801 Suspension of rules.

Upon notice to all parties, the responsible Department official or the Administrative Law Judge, with respect to matters pending before him/her, may modify or waive any rule in this part upon the determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 4.802 Definitions.

(a) The definitions set forth in § 17.12 of this title apply also to this subpart.

(b) "Director" means the Director, Office for Equal Opportunity, Department of the Interior.

(c) "Administrative Law Judge" means an Administrative Law Judge designated by the Office of Hearings and Appeals, Office of the Secretary, in accordance with 5 U.S.C. 3105 and 3344 (1976).

(d) "Notice" means a notice of hearing in a proceeding instituted under Part 17 of this title and these regulations.

(e) "Party" means a recipient or applicant, the Director, and any person or organization participating in a proceeding pursuant to § 4.808.

§ 4.803 Computation of time.

Except as otherwise provided by law, in computing any period of time under these rules or in any order issued hereunder, the time begins with the day following the act or event, and includes the last day of the period, unless it is a Saturday, Sunday, Federal legal holiday, or other nonbusiness day, in which event it includes the next following day which is not a Saturday, Sunday, Federal legal holiday, or other nonbusiness day. When the period of time prescribed or allowed is 7 days or less, intermediate Saturdays, Sundays, Federal legal holidays, and other nonbusiness days shall be excluded in the computation.

§ 4.804 Extensions of time.

A request for extension of time should be made to the designated Administrative Law Judge or other appropriate Departmental official with respect to matters pending before him/her. Such request shall set forth the reasons for the request and shall be served on all parties. Extensions may be granted upon a showing of good cause by the applicant. Answers to such requests are permitted if made promptly.

§ 4.805. Reduction of time to file documents.

For good cause, the responsible Departmental official or the Administrative Law Judge, with respect to matters pending before him/her, may reduce any time limit prescribed by the rules in this part, except as provided by law or in Part 17 of this title.

Designation and Responsibilities of Administrative Law Judge

§ 4.806 Designation.

Hearings shall be held before an Administrative Law Judge designated by the Office of Hearings and Appeals in accordance with 5 U.S.C. 3105 and 3344 (1976).

§ 4.807. Authority and responsibilities.

The Administrative Law Judge shall have all powers necessary to preside over the parties and the proceeding, to conduct the hearing, and to make a decision in accordance with 5 U.S.C. 554–557 (1976). These powers shall include, but are not limited to, the power to:

(a) Hold conferences to settle, simplify, or fix the issues in a proceeding, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(b) Require parties to state their position with respect to the various issues in the proceeding.

(c) Establish rules for media coverage of the proceeding.

(d) Rule on motions and other procedural items in matters before him/her.

(e) Regulate the course of the hearing, the conduct of counsel, parties, witnesses, and other participants.

(f) Administer oaths, call witnesses on his/her own motion, examine witnesses, and direct witnesses to testify.

(g) Receive, rule on, exclude, or limit evidence.

(h) Fix time limits for submission of written documents in matters before him/her.

(i) Take any action authorized by these regulations, by 5 U.S.C. 556 (1976), or by other pertinent law.

Appearance and Practice

§ 4.808 Participation by a party.

Subject to the provisions contained in Part 1 of this subtitle, a party may appear in person, by representative, or by counsel, and may participate fully in any proceeding held pursuant to Part 17 of this title and these regulations. A state agency or any instrumentality thereof, a political subdivision of the state or instrumentality thereof, or a corporation may appear by any of its officers or employees duly authorized to appear on its behalf.

§ 4.809 Determination of parties.

(a) The affected applicant or recipient to whom a notice of hearing or a notice of an opportunity for hearing has been mailed in accordance with Part 17 of this title and § 4.815, and the Director, are the initial parties to the proceeding.

(b) Other persons or organizations shall have the right to participate as parties if the final decision could directly and adversely affect them or the class they represent, and if they may contribute materially to the disposition of the proceeding.

(c) A person or organization wishing to participate as a party under this section shall submit a petition to the Administrative Law Judge within 15 days after the notice has been served. The petition should be filed with the Administrative Law Judge and served on the affected applicant or recipient, on the Director, and on any other person or organization who has been made a party at the time of filing. Such petition shall concisely state: (1) Petitioner's interest in the proceeding, (2) how participation as a party will contribute materially to the disposition of the proceeding, (3) who will appear for petitioner, (4) the issues on which petitioner wishes to participate, and (5) whether petitioner intends to present witnesses.

(d) The Administrative Law Judge shall promptly ascertain whether there are objections to the petition. The Administrative Law Judge shall then determine whether petitioners have the requisite interest to be a party in the proceeding, as defined in paragraphs (a) and (b) of this section, and shall permit or deny participation accordingly. Where petitions to participate as parties are made by individuals or groups with common interests, the Administrative Law Judge may request all the

petitioners to designate a single representative, or may recognize one or more of the petitioners to represent all the petitioners. The Administrative Law Judge shall give each petitioner written notice of the decision on a petition. If a petition is denied, the Administrative Law Judge shall briefly state the grounds for denial and shall then treat the petition as a request for participation as amicus curiae. The Administrative Law Judge shall give written notice to each party of each petition granted.

(e) Persons or organizations whose petition for party participation is denied may appeal the decision to the Director, Office of Hearings and Appeals, within 7 days of receipt of denial. The Director, Office of Hearings and Appeals, will make the final decision for the Department to grant or deny the petition.

§ 4.810 Complainants not parties.

A person submitting a complaint pursuant to § 17.6 of this title is not a party to the proceeding governed by Part 17 of this title and these regulations, but may petition, after the proceeding is initiated, to become an amicus curiae. In any event, a complainant shall be advised of the time and place of the hearing.

§ 4.811 Determination and participation of amici.

(a) Any interested person or organization wishing to participate as amicus curiae in the proceeding shall file a petition before the commencement of the hearing. The petition shall concisely state petitioner's interest in the hearing and who will represent petitioner.

(b) The Administrative Law Judge will grant the petition if it is found that petitioner has an interest in the proceeding and may contribute materially to the disposition of the proceeding. The Administrative Law Judge shall give petitioner written notice of the decision on the petition.

(c) An amicus curiae is not a party and may not introduce evidence at a hearing but may only participate as provided in paragraph (d) of this section.

(d) An amicus curiae may submit a written statement of position to the Administrative Law Judge at any time prior to the beginning of a hearing, and shall serve a copy on each party. The amicus curiae may also file a brief or written statement on each occasion a decision is to be made or a prior decision is subject to review. The brief or written statement shall be filed and served on each party within the time limits applicable to the party whose position the amicus curiae supports; or if the amicus curiae does not support the position of any party, within the longest time limit applicable to any party at that particular stage of the proceeding.

(e) When all parties have completed their initial examination of a witness, any amicus curiae may request the Administrative Law Judge to propound specific questions to the witness. The Administrative Law Judge, in his/her discretion, may grant any such request if he/she believes the proposed additional testimony may assist materially in elucidating factual matters at issue between the parties and will not expand the issues.

Form and Filing of Documents

§ 4.812 Form.

Documents filed in a proceeding shall show the docket description and title of the proceeding, the party or amicus submitting the document, the dates signed, and the title, if any, and address of the signatory. The original will be signed in ink by the person representing the party or amicus. Copies need not be signed, but the name of the person signing the original shall be reproduced.

§ 4.813 Filing and service.

(a) All documents submitted in a proceeding shall be served on all parties. The original and two copies of each document shall be submitted for filing. Filings shall be made with the Administrative Law Judge or other appropriate Departmental official before whom the proceeding is pending. With respect to exhibits and transcripts of testimony, only originals need be filed.

(b) Service upon a party or amicus shall be made by delivering one copy of each document requiring service in person or by certified mail, return receipt requested, properly addressed with postage prepaid, to the party or amicus, or attorney or designated representative. Filing will be made in person or by certified mail, return receipt requested, to the Administrative Law Judge or other appropriate Departmental official before whom the proceeding is pending.

(c) The date of filing or of service shall be the day when the matter is deposited in the U.S. mail or is delivered in person.

§ 4.814 Certificate of service.

The original of every document filed and required to be served upon parties shall be endorsed with a certificate of service signed by the party or amicus curiae making service or by the attorney or representative, stating that such service has been made, the date of service, and the manner of service.

Procedures

§ 4.815 How a proceeding is commenced.

A proceeding is commenced by the Director by mailing to an applicant or recipient a notice of alleged noncompliance with the Act and the regulations thereunder. The notice shall include either a notice of hearing fixing a date therefor or a notice of an opportunity for a hearing as provided in § 17.8 of this title. The notice shall advise the applicant or recipient of the action proposed to be taken, the specific provisions of Part 17 of this title under which the proposed action is to be taken, and the matters of fact or law asserted as the basis of the action.

§ 4.816 Notice of hearing and response thereto.

A notice of hearing shall fix a date not less than 30 days from the date of service of the notice of hearing on matters alleged in the notice. If the applicant or recipient does not desire a hearing it should be so stated in writing, in which case the applicant or recipient shall have the right to further participate in the proceeding. Failure to appear at the time set for a hearing, without good cause, shall be deemed a waiver of the right to a hearing under section 602 of the Act and the regulations thereunder and consent to the making of a decision on such information as is available which may be presented for the record.

§ 4.817 Notice of opportunity to request a hearing and response thereto.

A notice of opportunity to request a hearing shall set a date not less than 20 days from service of the notice within which the applicant or recipient may file a request for a hearing, or may waive a hearing and submit written information and argument for the record, in which case the applicant or recipient shall have the right to further participate in the proceeding. When the applicant or recipient elects to file a request for a hearing, a time shall be set for the hearing at a date not less than 20 days from the date applicant or recipient is notified of the date set for the hearing. Failure of the applicant or recipient to request a hearing or to appear at the date set shall be deemed a waiver of the right to a hearing under section 602 of the Act and the regulations thereunder and consent to the making of a decision on such information as is available which may be presented for the record.

§ 4.818 Answer.

In any case covered by § 4.816 or § 4.817 the applicant or recipient shall file an answer. The answer shall admit or deny each allegation of the notice unless the applicant or recipient is

without knowledge, in which case the answer shall so state and the statement will be considered a denial. Failure to file an answer shall be deemed an admission of all allegations of fact in the notice. Allegations of fact in the notice not denied or controverted by answer shall be deemed admitted. Matters alleged in the answer as affirmative defenses shall be separately stated and numbered. The answer under § 4.816 shall be filed within 20 days from the date of service of the notice of hearing. The answer under § 4.817 shall be filed within 20 days of service of the notice of opportunity to request a hearing.

§ 4.819 Amendment of notice or answer.

The Director may amend the notice of hearing or opportunity for hearing once as a matter of course before an answer is filed, and each respondent may amend the answer once as a matter of course not later than 10 days before the date fixed for hearing but in no event later than 20 days from the date of service of the original answer. Other amendments of the notice or of the answer to the notice shall be made only by leave of the Administrative Law Judge. An amended notice shall be answered within 10 days of its service, or within the time for filing an answer to the original notice, whichever period is longer.

§ 4.820 Consolidated or joint hearings.

As provided in § 17.8(e) of this title, the Secretary may provide for proceedings in the Department to be joined or consolidated for hearing with proceedings in other Federal departments or agencies by agreement with such other departments or agencies. All parties to any proceedings consolidated subsequent to service of the notice of hearing shall be promptly served with notice of such consolidation.

§ 4.821 Motions.

Motions and petitions shall state the relief sought, the basis for relief, and the authority relied upon. If made before or after the hearing itself, these matters shall be in writing. If made at the hearing they may be stated orally, but the Administrative Law Judge may require that they be reduced to writing and filed and served on all parties. Within 8 days after a written motion or petition is served, any party may file a response to a motion or petition. An immediate oral response may be made to an oral motion. Oral argument on motions will be at the discretion of the Administrative Law Judge.

§ 4.822 Disposition of motions.

The Administrative Law Judge may not grant a written motion or petition prior to expiration of the time for filing responses thereto, but may overrule or deny such motion or petition without awaiting response: *Provided however,* That prehearing conferences, hearings, and decisions need not be delayed pending disposition of motions or petitions. Oral motions and petitions may be ruled on immediately.

§ 4.823 Interlocutory appeals.

Except as provided in § 4.809(e), a ruling of the Administrative Law Judge may not be appealed to the Director, Office of Hearings and Appeals, prior to consideration of the entire proceeding by the Administrative Law Judge, unless permission is first obtained from the Director, Office of Hearings and Appeals, and the Administrative Law Judge has certified the interlocutory ruling on the record or abused his/her discretion in refusing a request to so certify.

Permission will not be granted except upon a showing that the ruleing complained of involves a controlling question of law and that an immediate appeal therefrom may materially advance the final decision. An interlocutory appeal shall not operate to suspend the hearing unless otherwise ordered by the Director, Office of Hearings and Appeals. If an appeal is allowed, any party may file a brief within such period as the Director, Office of Hearings and Appeals, directs. Upon affirmance, reversal, or modification of the Administrative Law Judge's Interlocutory ruling or order by the Director, Office of Hearings and Appeals, the case will be remanded promptly to the Administrative Law Judge for further proceedings.

§ 4.824 Exhibits.

Proposed exhibits shall be exchanged at the prehearing conference, or otherwise prior to the hearing if the Administrative Law Judge so directs. Proposed exhibits not so exchanged in accordance with the Administrative Law Judge's order may be denied admission as evidence. The authenticity of all exhibits submitted prior to the hearing, under direction of the administrative Law Judge, will be deemed admitted unless written objection thereto is filed and served on all parties, or unless good cause is shown for failure to file such written objection.

§ 4.825 Admissions as to facts and documents.

Not later than 15 days prior to the date of the hearing any party may serve upon an opposing party a written request for the admission of the genuineness and authenticity of any relevant documents described in, and exhibited with, the request, or for the admission of the truth of any relevant matters of fact stated in the request. Each of the matters as to which an admission is requested shall be deemed admitted, unless within a period of 10 days the party to whom the request is directed serves upon the requesting party a statement either (a) denying specifically the matters as to which an admission is requested, or (b) setting forth in detail the reasons why the matters cannot be either truthfully admitted or denied.

§ 4.826 Discovery.

(a) *Methods.* Parties may obtain discovery as provided in these rules by depositions, written interrogatories, production of documents, or other items; or by permission to enter property for inspection and other purposes.

(b) *Scope.* Parties may obtain discovery regarding any matter not privileged which is relevant to the subject matter involved in the hearing.

(c) *Protective orders.* Upon motion by a party or by the person from whom discovery is sought, and for good cause shown, the Administrative Law Judge may make any order which justice requires to limit or condition discovery in order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.

(d) *Sequence and timing.* Methods of discovery may be used in any sequence. The fact that a party is conducting discovery shall not operate to delay any other party's discovery.

(e) *Time limit.* Discovery by all parties will be completed within such time as the Administrative Law Judge directs from the date the notice of hearing is served on the applicant or recipient.

§ 4.827 Depositions.

(a) A party may take the testimony of any person, including a party, by deposition upon oral examination. This may be done by stipulation or by notice, as set forth in paragraph (b) of this section. On motion of any party or other person upon whom the notice is served, the Administrative Law Judge may, for cause shown, enlarge or shorten the time for the deposition, limit the scope of the deposition, or quash the notice. Depositions of persons other than parties or their representatives shall be upon consent of the deponent.

(b)(1) The party will give reasonable notice in writing to every other party of the time and place for taking depositions, the name and address of each person to be examined, if known, or a general description sufficient to identifying him/her or the particular class or group to which he/she belongs.

(2) The notice to a deponent may be accompanied by a request for the production of documents and tangible things at the taking of the deposition.

(3) A party may name as the deponent a corporation, partnership, association, or governmental agency and may designate a particular person within the organization whose testimony is desired and the matter on which examination is requested. If no particular person is named, the organization shall designate one or more agents to testify on its behalf, and may set forth the matters on which each will testify. The persons so designated shall testify as to matters known or reasonably available to the organization.

(c) Examination and cross-examination of witnesses may proceed as permitted at the hearing. The witness shall be placed under oath by a disinterested person qualified to administer oaths by the laws of the United States or of the place where the examination is held, and the testimony taken by such person shall be recorded verbatim.

(d) During the taking of a deposition a party or deponent may request suspension of the deposition on the grounds of bad faith in the conduct of the examination, annoyance, embarrassment, oppression of a deponent or party, or improper questions propounded. The deposition will then be adjourned. However, the objecting party of deponent must immediately move the Administrative Law Judge for a ruling on the objections to the deposition conduct or proceeding. The Administrative Law Judge may then limit the scope or manner of the taking of the deposition.

(e) The officer shall certify the deposition and promptly file it with the Administrative Law Judge. Documents or true copies of documents and other items produced for inspection during the examination of the witness shall, upon the request of a party, be marked for identification and annexed to the deposition.

(f) The party taking the deposition shall give prompt notice of its filing to all other parties.

§ 4.828 Use of depositions at hearing.

(a) Any part or all of a deposition so far as admissible under § 4.835 applied as though the witness were then present and testifying, may be used against any party who was present or represented at the taking of the deposition or who had reasonable notice thereof as follows:

(1) Any deposition may be used for contradiction or impeachment of the deponent as a witness.

(2) The deposition of a party, or of an agent designated to testify on behalf of a party, may be used by an adverse party for any purpose.

(3) The deposition of any witness may be used for any purpose if the party offering the deposition has been unable to procure the attendance of the witness because he/she is dead; or if the witness is at a greater distance than 100 miles from the place of hearing or is out of the United States, unless it appears that the absence of the witness was procured by the party offering the deposition; or if the witness is unable to attend or testify because of age, illness, infirmity, or imprisonment; or upon application and notice that such exceptional circumstances exist as to make it desirable, in the interest of justice and with due regard to the importance of presenting the testimony of witnesses orally in open hearing, to allow the deposition to be used.

(b) If only part of a deposition is offered in evidence, the remainder becomes subject to introduction by any party.

(c) Objection may be made at the hearing to receiving in evidence any depostion or part thereof for any reason which would require the exclusion of the evidence if the witness were then present and testifying.

§ 4.829 Interrogatories to parties.

(a) Any party may serve upon any other party written interrogatories after the notice of hearing has been filed. If the party served is a corporation, partnership, association, or governmental agency, an agent shall furnish such information as is available to the party.

(b) Each interrogatory shall be answered separately and fully in writing under oath, unless it is objected to in which event the objection shall be stated in place of an answer. The answers are to be signed by the persons making them, and the objections signed by the attorney or other representative making them. Answers and objections shall be made within 30 days after the service of the interrogatories. The party submitting the interrogatories may move for an order under § 4.831 with respect to any objection to or other failure to answer an interrogatory.

(c) Interrogatories shall relate to any matter not privileged which is relevant to the subject matter of the hearing.

§ 4.830 Production of documents and things and entry upon land for inspection and other purposes.

(a) After the notice of hearing has been filed, any party may serve on any other party a request to produce and/or permit the party, or someone acting on his/her behalf, to inspect and copy any designated documents, phonorecords, and other data compilations from which information can be obtained and which are in the possession, custody, or control of the party upon whom the request is served. If necessary, translation of data compilations shall be done by the party furnishing the information.

(b) After the notice of hearing has been filed, any party may serve on any other party a request to permit entry upon designated property in the posssession or control of the party upon whom the request is served for the purpose of inspection, measuring, surveying or photographing, testing, or sampling the property or any designated object.

(c) Each request shall set forth with reasonable particularity the items to be inspected and shall specify a reasonable time, place, and manner of making the inspection and performing the related acts.

(d) The party upon whom the request is served shall respond within 15 days after the service of the request. The response shall state, with respect to each item, that inspection and related activities will be permitted as requested, unless there are objections in which case the reasons for each objection shall be stated. The party submitting the request may move for an order under § 4.831 with respect to any objection to or other failure to respond.

§ 4.831 Sanctions.

(a) A party, upon reasonable notice to other parties and all persons affected thereby, may move for an order as follows:

(1) If a deponent fails to answer a question propounded or submitted under § 4.827(c), or a corporation or other entity fails to make a designation under § 4.827(b)(3), or a party fails to answer an interrogatory submitted under § 4.829, or a party under § 4.830 fails to respond that inspection will be permitted or fails to permit inspection, the discovering party may move for an order compelling an answer, a designation, or inspection.

(2) An evasive or incomplete answer is to be treated as a failure to answer.

(b) If a party or an agent designated to testify fails to obey an order to permit discovery, the Administrative Law Judge may make such orders as are just, including:

(1) That the matters regarding which the order was made or any other designated facts shall be established in accordance with the claim of the party obtaining the order.

(2) Refusing to allow the disobedient party to supoort or oppose designated claims or defenses, or prohibiting him/her from introducing designated matters in evidence.

(c) If a party or an agent designated to testify fails after proper service (1) to appear for the deposition, (2) to serve answers or objections to interrogatories submitted under § 4.829, or (3) to serve a written response to a request for inpection submitted under § 4.830, the Administrative Law Judge on motion may make such orders as are just, including those aughorized under subparagraphs (1) and (2) of paragraph (b) of this section.

§ 4.832 Ex parte communications.

(a) Written or oral communications involving any substantive or procedural issue in a matter subject to these proceedings directed to the Administrative Law judge, the Director, or the Director, Office of Hearings and Appeals, shall be deemed ex parte communications and are not to be considered part of any record or the basis for any official decision, unless the communication is made by motion pursuant to these rules.

(b) The Administrative Law Judge shall not consult any person or party on any fact in issue or on the merits of the matter before him/her unless upon notice and opportunity for all parties to participate.

(c) No employee or agent of the Federal Government engaged in the investigation and prosecution of a proceeding governed by these rules shall participate or advise in the rendering of any recommended or final decision, except as witness or counsel in the proceeding.

Prehearing

§ 4.833 Prehearing conferences.

(a) Within 15 days after the answer has been filed, the Administrative Law Judge will establish a prehearing conference date for all parties including persons or organizations whose petition requesting party status has not been ruled upon. Written notice of the prehearing conference shall be sent by the Administrative Law Judge.

(b) At the prehearing conference the following matters, among others, shall be considered: (1) Simplification and delineation of the issues to be heard; (2) stipulations; (3) limitation of number of witnesses and exchange of witness lists; (4) procedure applicable to the proceeding; (5) offers of settlement; and (6) scheduling of the dates for exchange of exhibits. Additional prehearing conferences may be scheduled at the discretion of the Administratiove Law Judge, upon his/her own motion or the motion of a party.

Hearing

§ 4.834 Purpose

(a) The purpose of a hearing is primarily to receive factual evidence and expert opinion testimony related to the issues in the proceeding. A hearing will be held only in cases where issues of fact must be resolved in order to determine whether the applicant or recipient has failed to comply with one or more applicable requirements of Title VI of the Civil Rights Act of 1964 and Part 17 of this title. However, this shall not prevent the parties from entering into a stipulation of the facts.

(b) If all facts are stipulated, the proceeding shall go to conclusion in accordance with Part 17 of this title and the rules in this subpart.

(c) In any case where it appears from the answer of the applicant or recipient to the notice of hearing or notice of opportunity to request a hearing, from the failure to timely answer, or from the admissions or stipulations in the record that there are no matters of material fact in dispute, the Administrative Law Judge may enter an order so finding, vacating the hearing date if one has been set, and fixing the time for the submission of evidence by the Government for the record. Thereafter, the proceeding shall go to conclusion in accordance with Part 17 of this title and the rules in this subpart. An appeal from such order may be allowed in accordance with the rules for interlocutory appeal in § 4.823.

§ 4.835 Evidence.

Formal rules of evidence will not apply to the proceeding. Irrelevant, immaterial, unreliable, and unduly repetitious evidence will be excluded from the record of a hearing. Hearsay evidence shall not be inadmissible as such.

§ 4.836 Official notice.

Whenever a party offers a public document, or part thereof, in evidence, and such document, or part thereof, has been shown by the offeror to be reasonably available to the public, the document need not be produced or marked for identification, but may be offered for official notice as a public document item by specifying the document or relevant part thereof. Official notice may also be taken of other matters at the discretion of the Administrative Law Judge.

§ 4.837 Testimony.

Testimony shall be given under oath by witnesses at the hearing. A witness shall be available for cross-examination, and, at the discretion of the Administrative Law Judge, may be cross-examined without regard to the scope of direct examination as to any matter which is material to the proceeding.

§ 4.838 Objections.

Objections to evidence shall be timely and the party making them shall briefly state the ground relied upon.

§ 4.839 Exceptions.

Exceptions to rulings of the Administrative Law Judge are unnecessary. It is sufficient that a party, at the time the ruling of the Administrative Law Judge is sought, makes known the action which he/she desires the Administrative Law Judge to take, or his/her objection to an action taken and the ground therefor.

§ 4.840 Offer of proof.

An offer of proof made in connection with an objection taken to any ruling of the Administrative Law Judge excluding proffered oral testimony, shall consist of a statement of the substance of the evidence which counsel contends would be adduced by such testimony. If the excluded evidence consists of evidence in written form or consists of reference to documents, a copy of such evidence shall be marked for identification and shall accompany the record as the offer of proof.

§ 4.841 Official transcript.

An official reporter will be designated for all hearings. The official transcripts of testimony and argument taken, together with any exhibits, briefs, or memoranda of law filed therewith, shall be filed with the Administrative Law Judge. Transcripts may be obtained by the parties and the public from the official reporter at rates not to exceed the applicable rates fixed by the contract with the reporter. Upon notice to all parties, the Administrative Law Judge may authorize such corrections to the transcript as are necessary to accurately reflect the testimony.

Posthearing Procedures

§ 4.842 Proposed findings of fact and conclusions of law.

Within 30 days after the close of the hearing each party may file, or the Administrative Law Judge may request, proposed findings of fact and conclusions of law together with supporting briefs. Such proposals and briefs shall be served on all parties and

amici. Reply briefs may be submitted within 15 days after receipt of the initial proposals and briefs. Reply briefs should be filed and served on all parties and amici.

§ 4.843 Record for decision.

The Administrative Law Judge will make a decision upon the basis of the record before him/her. The transcript of testimony, exhibits, and all papers, documents, and requests filed in the proceeding shall constitute the record for decision and may be inspected and copied.

§ 4.844 Notification of right to file exceptions.

The provisions of § 17.9 of this title govern the making of decisions by Administrative Law Judges, the Director, Office of Hearings and Appeals, and the Secretary. An Administrative Law Judge shall, in any initial decision made by him/her, specifically inform the applicant or recipient of the right under § 17.9 of this title to file exceptions with the Director, Office of Hearings and Appeals. In instances in which the record is certified to the Director, Office of Hearings and Appeals, or in which the Director, Office of Hearings and Appeals, reviews the decision of an Administrative Law Judge, he/she shall give the applicant or recipient a notice of certification or notice of review which specifically informs the applicant or recipient that, within a stated period which shall not be less than 30 days after service of the notice, the applicant or recipient may file briefs or other written statements of the contentions.

§ 4.845 Final review by Secretary.

Paragraph (f) of § 17.9 of this title requires that any final decision of an Administrative Law Judge or of the Director, Office of Hearings and Appeals, which provides for the suspension or termination of or the refusal to grant or continue Federal financial assistance, or the imposition of any other sanction available under Part 17 of this title or the Act, shall be transmitted to the Secretary. The applicant or recipient shall have 20 days following service upon him/her of such notice to submit to the Secretary exceptions to the decision and supporting briefs or memoranda suggesting remission or mitigation of the sanctions proposed. The Director shall have 10 days after the filing of the exceptions and briefs in which to reply.

Subpart K—[Deleted]

4. It is proposed to delete Subpart K of Title 43 of the *Code of Federal Regulations* because the deadline for disenrollment contest review (October 1, 1978) has passed (*see* 25 CFR 43 h. 15 (h)).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 400

Refugee Resettlement Program; Plan and Reporting Requirements for States

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed regulation sets forth the plan requirements a State must meet as a condition for receiving assistance for refugees under title IV of the Immigration and Nationality Act. It also includes requirements for the establishment of advisory councils to participate in the implementation of the plan, requirements for the content of the State annual report on the use of refugee resettlement program funds, and requirements for maintenance of records. This proposed regulation implements section 412(a)(6) of the Immigration and Nationality Act (added by section 311(a)(2) of the Refugee Act of 1980), that requires a State, as a condition for receiving assistance for refugees, to submit to the Director of the Office of Refugee Resettlement (ORR) (1) a plan that provides details of the State's program for delivering assistance and services funded by ORR, and (2) an annual report, after the end of each fiscal year, on the use of State-administered Federal funds provided under the program. State plans must be submitted by October 1, 1980, the first annual report is due December 1, 1980; advisory councils must be established by January 1, 1981.

DATE: To assure consideration, comments should be received by June 26, 1980.

ADDRESS: Address comments to:

Director, Office of Refugee Resettlement, Department of Health and Human Services, Room 1229 Switzer Building, 300 C Street, SW., Washington, D.C. 20201.

Agencies and organizations are requested to submit comments in duplicate. Comments will be available approximately two weeks after publication in Room 1229, 330 C Street, SW. on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Dennis Gallagher, Office of Refugee Resettlement, 1229 Switzer Building, 330 C Street, SW., Washington, D.C. 20201, (202) 426-6510.

SUPPLEMENTARY INFORMATION:

Background

The Migration and Refugee Assistance Act of 1962 centralized the authority to conduct and fund U.S. programs of assistance to refugees. This Act is the legal basis for most of the U.S. migration and refugee assistance programs. The legislation provided an open-ended authorization for assistance to Cuban refugees in the United States.) The 1965 amendments to the Immigration and Nationality Act established the first permanent statutory basis for the admission of refugees.

The Migration and Refugee Assistance Act of 1962 was authorized for Western Hemisphere refugees only. With the influx of Indochinese refugees in 1975, the Indochina Migration and Refugee Assistance Act of 1975 was passed to authorize assistance to Indochinese refugees. The 1975 act was amended four times to include Laotian refugees and to extend the authorization period for domestic assistance. Assistance was provided through the Indochinese Refugee Assistance Program (IRAP) within the Department of Health, Education, and Welfare (now HHS).

Under IRAP, States entered into agreements with HHS wherein they agreed to provide cash and medical assistance and support services to Indochinese refugees in accordance with program instructions, policies, and procedures issued by HHS' Social Security Administration. They also agreed to maintain records, make reports, and account for all Federal funds received under the program. Program guidelines were issued to States by administrative instructions because the program authority was to be temporary. Because of the continued growth of the program and the expectation of continued refugee admittance, a more formal and uniform base for program operations and management was needed.

On March 17, 1980, the President signed the Refugee Act of 1980 (Pub. L. 96-212) which, among other things, amended the Immigration and Nationality Act to revise procedures for the admission of refugees, and the Migration and Refugee Assistance Act of 1962 to establish a more uniform basis for the provision of assistance to

refugees. Section 311 of Pub. L. 96–212 amended title IV of the Immigration and Nationality Act to establish the Office of Refugee Resettlement (ORR) in HHS. The function of ORR and its Director is to fund and administer domestic refugee resettlement programs of the Federal government. Pub. L. 96–212 also requires (1) detailed monitoring and evaluation of the resettlement program; (2) detailed reports to the Congress on the operation of the program and the activities of ORR; and (3) States to submit a plan to the Director, by October 1, 1980 and (4) annual State reports on the uses of Federal funds in the preceding fiscal year.

Statutory Authority

This proposed regulation would implement section 412(a)(6) of the Immigration and Nationality Act. That section, added by section 311(a)(2) of the Refugee Act of 1980, requires States, as a condition for receiving refugee assistance, to—

(1) Submit a plan to the Director of ORR;

(2) Meet standards, goals, and priorities, developed by the Director of ORR, which assure the effective resettlement of refugees and which promote their economic self-sufficiency expeditiously and the efficient provision of services; and

(3) Submit to the Director, after the end of the fiscal year, a report on the uses of resettlement funds administered by the State.

Under section 313(d) of the Refugee Act of 1980, the requirements for a plan apply to assistance furnished after October 1, 1980. Section 412(a)(9) of the Immigration and Nationality Act authorizes the Secretary of HHS to issue regulations needed to carry out the program.

We intend to develop regulations over the next year governing the refugee resettlement program after consultation with States, private voluntary resettlement organizations, refugee groups, and others. After a thorough examination of the legislation and current program policy, as well as these various consultations, we will issue program regulations on those aspects of the legislation that are deemed most appropriate to implement the law effectively and achieve its purpose of establishing a more uniform basis for the provision of assistance to refugees.

However, the legislation requires that States, to receive funds for refugee resettlement, submit a plan to the Director of ORR by October 1, 1980. In order to meet that deadline we are publishing this proposed regulation with an expedited public comment period of 30 days. We believe it is important for States to receive guidance before they submit their plans required by the statute. This propoed regulation sets forth plan requirements contained in the statute, a requirement for establishing an advisory council, and minimal reporting requirements. The expedited comment period will ensure that States have as much advance notice and guidance as possible given the limited time frame between passage of the statute and the due date of plans.

Agreements between HHS and States remain in effect until September 30, 1980. By October 1, 1980, a State must have submitted a plan meeting the requirements to the Director of ORR in order to continue to receive assistance. States may continue to rely on program instructions and action transmittals issued under IRAP for guidance, to the extent that they do not conflict with the current statute, until the program regulations to be developed over the next year are published.

Section 301 of the Refugee Act of 1980 amends section 101(a) of the Immigration and Nationality Act by adding a new definition of the term "refugee". Inasmuch as the Department of Justice is charged with determining refugee status and creating appropriate requirements to document this status, the following proposed regulation is tied to these initial determinations and requirements. The Department of Justice is presently developing interim regulations covering these matters. Until those regulations are implemented, the current practices and procedures utilized by the Department of Justice in establishing refugee status should be referred to by States in formulating plans under the accompanying proposed regulation.

Description of the Regulation

The proposal sets forth (1) the plan requirements contained in the statute; (2) the requirement for establishing a State advisory council to participate in the development and review of plan amendments submitted to ORR; (3) the required content of the annual State report on the uses of Federal funds provided for refugee assistance; and (4) the requirement for maintenance of records.

All requirements proposed in these regulations are statutorily imposed with the following exceptions:

(1) The establishment of the provision of English language training and employment services as a priority in accomplishing the purpose of the program (§ 400.1(c));

(2) The designation of a single State agency responsible for the development and administration of the plan (§ 400.4(a));

(3) The establishment of, and consultation with the State advisory council (§ 400.4(g) and § 400.8);

(4) The submittal of plans for the Governor's review § 400.6);

(5) The maintenance of records and the content of the annual report (§ 400.9); and

(6) The confidentiality of records (§ 400.10).

We welcome comments on any of these provisions in the proposed regulations. We are legally bound to implement statutorily imposed requirements.

Plan Requirements

Section 412(a)(6)(A) of the Immigration and Nationality Act requires a State, in order to receive Federal funds under the refugee resettlement program, to submit a plan. This proposal sets forth the basic elements that must be included in each plan, including the designation of a single state agency to develop and administer the plan. The proposal requires a plan to describe how the State intends to encourage effective refugee resettlement and to promote economic self-sufficiency as quickly as possible, through the provision of cash and medical assistance and other support services. We believe that a concerted effort must be made to provide vital services to refugees as soon as possible after their arrival and to begin immediately to enhance their economic and social self-sufficiency and reduce future dependence on public welfare. Support services, as well as cash and medical assistance, are among these vital types of aid.

The proposal would require a plan to describe the State program that would ensure that language training and employment services are available for refugees. In addition, States would be required to describe efforts to actively encourage refugee registration for employment services. Section 412(e)(2)(A) of the Act requires that, as a pre-condition to receiving cash assistance, refugees must register with an appropriate agency providing employment services described in section 412(c)(1) of the Act or, if there is no such agency available, with an appropriate State or local employment service. This precondition does not apply during the first 60 days after the date of the refugee's entry to this country.

Congress, as well as HHS, has placed strong emphasis on the provision of

language training and employment-related services as a means of achieving our goal of assisting refugees in becoming self-sufficient in their new environment. Program policy in the past has enabled States to emphasize those services most urgently needed by refugees for self-sufficiency and adaptation. Therefore, Congress included in the legislation the requirement that a plan describe how the State will ensure that such training and services are made available to refugees receiving cash assistance.

Section 412(a)(6)(B) of the Act gives the Director the authority to establish priorities that assure the effective resettlement of refugees and promote their economic self-sufficiency as quickly as possible. The Director has exercised that authority in establishing the provision of English language training and employment services as a priority in accomplishing the purpose of the program.

The proposed regulation requires a plan to provide for the care and supervision of, and legal responsibility for, unaccompanied refugee children in the State. Congress expressed concern for unaccompanied refugee children who have not been admitted to this country because of problems of custody, guardianship, and responsibility for providing services to these children. The legislation clarifies legal custody and financial responsibility issues and requires States to provide for the care and supervision of unaccompanied refugee minors. This clarification should encourage State governments and voluntary resettlement agencies to expand their efforts to assist these children.

The proposal requires the plan to provide for the designation of an individual to be called the Coordinator, who is employed by the State and will have the responsibility to develop necessary services and ensure coordination of public and private resources in refugee resettlement. The designated individual would prevent duplication of effort and services through coordination of available resources for refugees.

Under the proposed regulation, a State is required to provide in its plan for the identification of refugees who, at the time of resettlement in the State, are determined to have medical conditions requiring, or medical histories indicating a need for, treatment or observation, and monitoring of any necessary treatment or observation. As more refugees have entered the country, there has been increased community concern that health standards might be threatened. HHS has tightened health screening procedures in Southeast Asia and at ports-of-entry to the United States. However, we believe that early identification of refugees who have medical conditions requiring treatment or observation will avoid any threat to our health standards and help meet refugees' immediate health needs.

Although States must establish a State advisory council responsible for assisting in the development and review of any plan amendments after January 1, 1981, the proposal includes a requirement that the plan specify the composition of the State advisory council and describe how the State will ensure that the council will be organized and operating by January 1, 1981.

The statute requires that assistance and services funded under the plan be provided without regard to race, religion, nationality, sex or political opinion. The proposed regulation requires the plan to include such an assurance. Finally, the plan would be required to provide that the State will comply with the provisions of title IV of the Immigration and Nationality Act and Federal policy issued by the Director, and will amend the plan as needed to comply with standards, goals, and priorities established by the Director.

The plan must be submitted to the Governor for review and comment prior to its submittal to the Director, in accordance with Part III of OMB Circular A-95. We want to emphaisize that all States wishing to receive refugee funds for cash or medical assistance or services, regardless of the scope of their program, must submit a plan that complies with the requirements, to the Director of ORR by October 1, 1980, and an annual report by December 1, 1980, of each year. We request that States inform the Director by August 1, 1980 of their intent to file a plan.

State Advisory Councils

The proposal would require States to establish advisory councils, by January 1, 1981, that would be responsible for assisting the State in the development of any plan amendment, and reviewing any plan amendment prior to its submittal to ORR. Reasonable and necessary costs associated with the operation of the State advisory council are reimbursable as State administrative costs. Because of the time involved in establishing such a council, we have not required that the council be in place in time to review the initial plan prior to its submittal. However, States must consult with councils when developing any plan amendment after January 1, 1981, and provide for the council's review of any plan amendment after that date.

The council would have no less than five and no more than 15 members, and would be composed of representatives of refugees eligible to benefit from services under the plan by virtue of being a refugee, local government, voluntary resettlement organizations, and service providers.

Historically, the resettlement of refugees has involved both the public and private sector working in cooperation to meet the particular resettlement needs of various refugee groups. As refugees have gained experience in the United States, they have become an increasingly important resource in the resettlement program. Having undergone the process themselves, being able to communicate with incoming refugees, and being able to understand the problems and needs of this group, well-adapted refugees can contribute significantly to the successful adjustment of those who will arrive in the future. The voluntary agencies are clearly in a position of great responsibility in the resettlement program, being involved deeply in the sponsorship, transit, and placement of refugees in the United States. The role local governments and service providers play in easing refugees' resettlement in this country is equally valuable to the process. These sources' combined knowledge, and commitment to, and concerns for, refugees' quick economic and social adjustment make their involvement in the process of developing the plan amendments invaluable to the program effectiveness we hope to achieve. Therefore, the proposal would require their involvement in the process through State consultation with an advisory council of representatives from each group.

Maintenance of Records and Annual Reports on Uses of Funds

Section 412(2)(6)(C) of the Immigration and Nationality Act requires that, as a condition for receiving funds under the refugee resettlement program, a State must submit, within a reasonable period of time after the end of each fiscal year, a report to the Director on the uses of State-administered Federal funds. This proposal sets forth requirements for minimal data to be included in State reports due by December 1 of each year covering the activities of the preceding fiscal year, and basic requirements for the maintenance of records necessary for reporting and accountability required by the Congress.

The annual reports would include a narrative statement on the progress, problems, and proposed actions to resolve problems encountered by the State. In addition, reports would include

data on State cash and medical assistance and support services caseloads; the numbers of refugees receiving language and employment-related services; the status and progress of each unaccompanied refugee child; and expenditures for cash and medical assistance (by type of service), support services (by type of service), and administrative costs. We also propose minimal requirements for basic maintenance of State records and confidentiality of those records.

Both HHS and the Congress have expressed the need for increased coordination, closer minitoring, and greater accountability in the uses of Federal refugee resettlement funds. Congress expressed concern that the refugee resettlement program established by the Refugee Act of 1980 be carefully monitored and evaluated. The legislation places reporting requirements on the States, the Director of ORR, and the Secretary of HHS. These requirements include detailed monitoring and evaluation of the resettlement program, reports to the Congress on program operation and ORR activities, and annual State reports to ORR on the use of Federal funds received in the preceding fiscal year.

In order for us to meet Congressional expectations on the accountability of this program, States must provide us with information on their programs. We do not believe these proposed reporting and data requirements to be burdensome. They are necessary because of the formalization of the program and our responsibility to Congress concerning Federal expenditures for the effective and efficient resettlement of refugees.

45 CFR Chapter IV is amended by adding a new Part 400 to read as follows:

PART 400—REFUGEE RESETTLEMENT PROGRAM

Subpart A—Introduction

Sec.

Subpart B—General Requirements

Authority: Sec. 412(a)(9), Immigration and Nationality Act (8 U.S.C. 1522(a)(9)).

Subpart A—Introduction

§ 400.1 Basis and purpose of the program.

(a) This part prescribes requirements concerning grants to States under title IV of the Immigration and Nationality Act.

(b) It is the purpose of this program to provide for the effective resettlement of refugees and to assist them to achieve economic self-sufficiency as quickly as possible.

(c) Under the authority in sec. 412(a)(6)(B), the Director has established the provision of English language training and employment services as a priority in accomplishing the purpose of this program.

§ 400.2 Definitions.

The following definitions are applicable for purposes of this part:

"Act" means the Immigration and Nationality Act;

"Cash assistance" means financial assistance provided to refugees for which the State expects to seek funding from appropriations under title IV of the Immigration and Nationality Act;

"Coordinator" means the individual designated in the plan to be responsible for, and authorized to, ensure coordination of public and private resources in refugee resettlement;

"Director" means the Director, Office of Refugee Resettlement;

"HHS" means the Department of Health and Human Services;

"Medical assistance" means medical services provided to refugees for which the State expects to seek funding from appropriations under title IV of the Immigration and Nationality Act;

"ORR" means the Office of Refugee Resettlement;

"Plan" means a written commitment by a State, submitted under section 412(a)(6)(A) of the Act, to administer or supervise the administration of a refugee resettlement program in accordance with Federal requirements.

"Secretary" means the Secretary of the Department of Health and Human Services;

"Support services" means services provided by, or purchased by, a State, designed to meet resettlement needs of refugees, for which the State expects to seek funding from appropriations under title IV of the Immigration and Nationality Act; and

"State" means the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa and the Trust Territories of the Pacific.

"State agency" means the State agency designated by the Governor as responsible for developing and administering the plan under title IV of the Immigration and Nationality Act.

Subpart B—General Requirements

§ 400.3 Purpose of the plan.

(a) In order for a State to receive refugee resettlement assistance from the allotments of funds under sec. 414 of the Act, it must submit to the Director of ORR by October 1, 1980, a plan that the Director determines to meet the plan requirements in § 400.4.

(b) The plan is a statement submitted by the State describing the nature and scope of its program and giving assurances that the program will be administered in conformity with specific requirements stipulated in title IV of the Immigration and Nationality Act and official issuances by the Director. The plan contains information necessary for the Director to determine whether the plan meets the plan requirements under § 400.4 as a basis for Federal funding of the State program.

§ 400.4 Content of the plan.

The plan must:

(a) Provide for the designation of a single State agency responsible for the development and administration of the plan;

(b) Describe how the State will encourge refugee resettlement and promote economic self-sufficiency as quickly as possible, by providing cash assistance, medical assistance and support services;

(c) Describe how the State will ensure that language training and employment services are made available to refugees receiving cash assistance, and to other refugees, including State efforts to actively encourage refugee registration for employment services;

(d) Designate an individual with the title of Coordinator, who is employed by the State, and will have the responsibility and authority to ensure coordination of public and private resources in refugee resettlement;

(e) Provide for the care and supervision of, and legal responsibility for, unaccompanied refugee children in the State;

(f) Provide for and describe the procedures established to ensure the identification of refugees who, at the time of resettlement in the State, are determined to have medical conditions requiring, or medical histories indicating a need for, treatment or observation, and the monitoring of any necessary treatment or observation;

(g) Specify the composition of the State advisory council established in accordance with the requirements of

§ 400.8 and describe how the State will ensure that the council is organized and operating by January 1, 1981;

(h) Provide that assistance and services funded under the plan will be provided without regard to race, religion, nationality, sex or political opinion; and

(i) Provide that the State will comply with the provisions of title IV of the Act and Federal policy issued by the Director, and will amend the plan as needed to comply with standards, goals, and priorities established by the Director.

§ 400.5 Plan amendments.

A State's administration of the program under this part must conform with the plan submitted to the Director, and determined by the Director to meet the plan requirements in § 400.4. Before the State agency implements any material changes in the content or administration of the plan, it must submit an amendment to the plan to the Director.

§ 400.6 Submittal of plans for Governor's review.

A plan or plan amendment under title IV of the Act must be submitted to the State Governor for review and comment before the plan is submitted to the Director, unless the Governor delegates the authority to review and comment on the plan and plan amendment to the designated single State agency or Coordinator.

§ 400.7 Federal financed participation.

Federal financial participation will be made available under the plan to States for cash and medical assistance, refugee support services, and reasonable and necessary administrative costs of such assistance and services, provided to eligible refugees beginning October 1, 1980. The Director will establish quarterly allocations which will be communicated to States each quarter.

§ 400.8 State advisory council.

(a) A State must establish an advisory council responsible for assisting in the development and reviewing of any plan amendments after January 1, 1981.

(b) The State advisory council must be comprised of no less than five and no more than 15 members who are representatives from refugees eligible to benefit from services under the plan by virtue of being a refugee, local government, voluntary resettlement organizations, and service providers.

(c) The State must consult with the advisory council during the development of any plan amendment, and provide for the advisory council's review of the contents of a plan amendment prior to its submittal to the Director of ORR.

§ 400.9 Maintenance of records and annual report.

(a) A State must provide for the maintenance of such fiscal and operational records as are necessary for Federal monitoring. This recordkeeping must include, but not be limited to:

(1) Documentation of services and assistance provided, including identification of individuals receiving those services;

(2) Records on the progress and status of unaccompanied minor refugee children, including the last known address of parents;

(3) Documentation that necessary medical follow up services and monitoring have been provided;

(4) Fiscal records in a format specified by the Director; and

(5) Annual and other reports referred by the Director.

(b) In order for a State to receive refugee resettlement assistance from the allotment of funds under sec. 414 of the Act, it must submit an annual report to the Director of ORR, by December 1 of each year, on the uses of funds received and administered by the State in the previous fiscal year.

(c) The annual report must include—

(1) A narrative statement of the program status, including progress achieved, problems encountered, and proposed actions to resolve problems;

(2) State cash assistance, medical assistance and support services caseloads;

(3) The number of refugees receiving English language training services and a description of the services provided;

(4) The number of refugees receiving employment-related services and a description of the services provided;

(5) A report on the status and progress of each unaccompanied refugee child admitted to the State;

(6) Expenditures for cash assistance, medical assistance (by type of service), and support services (by type of service), and administrative costs; and

(7) Additional statistical, fiscal, and other information required by the Director to ensure proper accountability of all program funds.

§ 400.10 Confidentiality of records.

The State must ensure that no information about, or obtained from, an individual and in possession of any agency providing assistance or services to such individual under the plan, will be disclosed in a form identifiable with the individual without the individual's consent.

(Sec. 412(a)(9), Immigration and Nationality Act (8 U.S.C. 1522(a)(9))

Approved: May 19, 1980.

Patricia Roberts Harris,

Secretary of Health and Human Services.

[FR Doc. 80-15872 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-12-M

COMMUNITY SERVICES ADMINISTRATION

45 CFR Parts 1061, 1068, 1075

State Agency Assistance Funded Under Section 231 of the Economic Opportunity Act

AGENCY: Community Services Administration.

ACTION: Proposed amendment of a rule.

SUMMARY: The Community Services Administration is proposing to revise its policy statement implementing Section 231 (State Agency Assistance) of the Economic Opportunity Act of 1964 as amended. This rule is currently published at 45 CFR Part 1075 as Subpart 1075.1, State Economic Opportunity Offices. The proposed rule implements changes in legislation which were included in the Economic Opportunity Amendments of 1978 in addition to changes in administrative requirements.

DATE: CSA welcomes and encourages comments on the rule. Comments received prior to July 28, 1980, will be considered in writing the final rule.

ADDRESS: Please send all comments to: Ms. Jacqueline G. Lemire, Policy Development and Review Division, Community Services Administration, 1200 19th Street, NW., Washington, D.C. 20037.

FOR FURTHER INFORMATION CONTACT: Ms. Jacqueline G. Lemire, Telephone: 202-254-5047; Teletypewriter: 202-254-6218

SUPPLEMENTARY INFORMATION:

Significance of Regulation

CSA has determined that under its published criteria implementing Executive Order 12044 this is a significant change to a rule.

CSA is proposing to revise its existing policy implementing the provisions of Section 231 of the Economic Opportunity Act of 1964, as amended (45 CFR 1075.1). This proposed revision implements legislative changes mandated by the Economic Opportunity Amendments of 1978. In addition the policy is being revised to reflect the changing role of the States in anti-poverty activities in the ten year period since CSA published its present policy, e.g. they now have a

role in the administration of many major grant-in-aid programs, resources for anti-poverty programming at the State level have increased steadily, etc.

Given the need for flexibility in administering Federal programs at the State level, the amended rule would provide that the Governor of each state select the State agency which he or she wishes to receive funding under Section 231 of the EOA. This agency would have to be an agency within the State structure which meets criteria published in the rule. (See § 1061.90–4(a).) The agency selected also would be the agency to which CSA would provide prior notification of financial assistance under Section 222 of the Economic Opportunity Act.

Funds allocated by CSA for use by a State will be granted only to an agency selected by the Governor. If the Governor chooses not to select an agency, no other agency or organization within the State will receive funds under Section 231.

There would be a mandated set of goals which all designated agencies would be required to address along with acceptable activities. In addition these agencies could propose to address other prescribed goals if Section 231 funds were available above and beyond those required to carry out the mandated work program.

Grants made under this Section of the EOA would no longer carry a non-Federal share requirement.

Legislative changes are proposed to be implemented as follows: Goal #1 includes activities which implement the legislative amendment to Section 231 providing the Director of CSA with the authority to fund State agencies which, in turn, will assist programs funded under Sections 221 and 222 of the EOA in coordinating and utilizing services available through other State agencies. Goal #3 (§ 1061.90–5(a)(3)) and the Goal described in 90–(b)(2) implement the legislative change which includes advising the Director of CSA and the Governor on the problems of poverty.

The proposed rule governs only the goals and activities to be undertaken with funds awarded under Section 231. It does not address, nor does it intend to circumscribe, the activities of the State agency selected by the Governor or any other State agency which is provided financial assistance by CSA under other Sections of the Economic Opportunity Act.

The provisions of this rule would have to be fully implemented by July 1, 1981.

(Sec. 602, 78 Stat. 530; (42 U.S.C. 2942).)

Robert S. Landmann,

Acting Director.

45 CFR Chapter X is proposed to be amended as follows:

PART 1075—STATE ECONOMIC OPPORTUNITY OFFICES [DELETED]

1. Part heading 1075 is deleted.

§§ 1075.1–1—1075.1–11 (Subpart 1075.1) [Deleted]

2. Subpart 1075.1, Role of State Economic Opportunity Offices (CSA Instruction 7501–1) is deleted in its entirety.

PART 1068—GRANTEE FINANCIAL MANAGEMENT

Subpart 1068.20—Non-Federal-Share Requirements for Title II, Sections 221 and 222(a)

§§ 1068.20–2 and 1068.20–3 [Amended]

3. Subpart (1068.20)—Non-Federal-Share Requirements for Title II, Sections 221, 222(a) and 231, is amended by revising the title to read "Non-Federal-Share Requirements for Title II, Sections 221 and 222(a)"; by deleting paragraph "(b) Administrative requirement (231)" of § 1068.20–2 in its entirety; and by deleting paragraph (a)(4) SEOOs (Section 231.) of § 1068.20–3 in its entirety.

PART 1061—CHARACTER AND SCOPE OF SPECIFIC PROGRAMS

4. Part 1061 is amended by adding Subpart 1061.90 to read as follows:

Subpart 1061.90—State Agency Assistance Funded Under Section 231 of the Economic Opportunity Act

Sec.

Authority: Sec. 602, 78 Stat. 530; (42 U.S.C. 2942).

Subpart 1061.90—State Agency Assistance Funded Under Section 231 of the Economic Opportunity Act

1061.90–1 Applicability.

This subpart is applicable to grants, contracts, and cooperative agreements funded under Section 231 of the Economic Opportunity Act of 1964, as amended, when the assistance is administered by the Community Services Administration.

1061.90–2 Purpose.

The purpose of this subpart is to provide to State Governors criteria by which they may choose a State agency as the agency eligible to apply to the Community Services Administration for funds under Section 231 of the Economic Opportunity Act of 1964, as amended (EOA). This subpart also details the goals which are to be addressed with funds provided under Section 231; pre-funding requirements; the application process; and post-funding requirements.

1061.90–3 Timeframe for implementation of rule.

The provisions of this rule may be applied beginning (30 days after publication of the final rule in the Federal Register) but must be fully implemented by July 1, 1981 by any Governor who elects to apply for funding under Section 231.

1061.90–4 Procedures for selecting a State agency to receive assistance under Section 231 of the EOA.

(a) *How a State agency is selected.* The Governor of a State may select a State agency within his or her State as the agency will carry out those anti-poverty efforts described in this rule. The agency which the Governor selects also will be the agency to whom prior notification of financial assistance under Section 222 will be provided. The agency selected must be one (1) whose Director has direct line authority and responsibility for implementing the goals of a CSA-approved work program; (2) has direct organizational access to the Governor for the purposes of carrying out the Goals of the CSA-approved work program; (3) which has the demonstrated ability to mobilize State and Federal resources in support of the anti-poverty efforts of Community Action Agencies and other local anti-poverty groups; and (4) which has proven experience in planning, coordinating, administering or operating programs for the poor.

(b) *Determination of eligibility.* Sixty days prior to submission of an application for funding the agency selected by the Governor will be responsible for providing the appropriate CSA Regional Office with documents and other data and information by which the CSA Regional Director can verify eligibility of the agency. These supporting documents must address each of the elements described in paragraph (a)(1) through (4) of this section.

1061.90-5 Goals and eligible activities.

(a) *Mandated goals for all work programs.* CSA recognizes that States differ in their constitutional, statutory and organizational patterns. States also differ in terms of resources available, the causes of poverty, and the resulting programs. However, regardless of these differences CSA believes that the following are valid anti-poverty goals for all States. Therefore, Goals 1 through 3 listed below, along with their selected activities, must be addressed in *all* work programs:

(1) Goal #1: To increase the amounts and kinds of Federal, State and private resources available for anti-proverty activities within a State.

Acceptable activities in achieving this goal include but are not limited to:

(i) Seeking out, developing or assisting in the development of every State, local, Federal and non-Federal resource that can be marshalled effectively and/or coordinated to assist poor persons, Community Action Agencies, State community action associations, and other anti-proverty efforts within the state.

(ii) Developing and carrying out strategies for obtaining additional resources for new and existing anti-poverty activities of the State.

(iii) Initiating or stimulating the development and implementation of anti-proverty programs which are needed and not being provided adequately in the State.

(iv) Promoting the utilization of all available State resources by making necessary information and support available to poor persons.

(2) Goal #2: To strengthen State capabilities for planning and coordinating in order to insure that available assistance related to the elimination of poverty can be more responsive to the needs and conditions of the poor within a State.

Acceptable activities in achieving this goal include but are not limited to:

(i) Promoting the maximum feasible participation of poor people in the planning, conduct and evaluation of other State agency operations and programs which affect the poor.

(ii) Developing interagency mechanisms at the State and local program level to insure good communications between State and local agencies, particulary Community Action Agencies and State community action associations, and other agencies and offices whose activities affect the poor.

(iii) Developing a formal mechanism by which to advise departments of State government of the capabilities of Community Action Agencies and other CSA-funded anti-poverty groups to assist State agencies in their antipoverty efforts.

(iv) Working for representation of poor persons on State committees and other entities which develop policy, provide advice or operate programs affecting the poor.

(3) Goal #3: To assure that the Governor has current and expert advice and information on poverty problems and anti-poverty efforts within the State. Acceptable activities in achieving this goal include but are not limited to:

(i) Providing the Governor with information and advice with respect to the policies and programs of the Community Services Administration and other anti-proverty resources.

(ii) Providing the Governor, the State legislature, and other state agencies with information on the causes and conditions of poverty in the State.

(iii) Advising the Governor on the status and impact of State and Federal programs and services affecting poor individuals in the State.

(iv) Assisting the Governor in carrying out the provisions of Section 242 of the EOA.

(v) Drafting an Annual Report on Poverty in the State for delivery by the Governor to the State legislature and to the citizens of the State.

(b) *Supplementary goals and activities.* In those instances where a selected State agency has *funds available* under Section 231 *above and beyond those required to carry out its mandated work program* as described in paragraph (a) of this section, the agency may address one or more of the following in its proposed work program:

(1) Goal: To assure that Community Action Agencies and other CSA grantees have available to them the technical expertise and information and other assistance which will enable them to carry out effectively and efficiently their anti-proverty efforts.

(i) Acceptable activities in achieving this goal include:

(A) In consultation with CSA, assisting grantees in implementing corrective actions recommended by CSA as a result of evaluations, pre-reviews, monitoring and/or audit reports.

(B) In consultation with CSA, CSA grantees, and other anti-poverty groups, sponsoring or participating in training programs and workshops for staff and board members, utilizing state resources and personnel to the extent possible.

(C) Providing information and assistance to CAAs, other CSA grantees, and other anti-poverty groups, in planning, developing and operating programs including volunteer programs.

(2) Goal: To assure that the Director of CSA has current and expert information on the impediments to coordinating anti-poverty programs at the State level and how these impediments may be eliminated.

(i) Acceptable activities in achieving this goal include:

(A) Advising and assisting CSA in identifying problems posed by Federal and State statutory or administrative requirements that impede state-level coordination of CSA-related programs, and in developing methods or recommendations for overcoming these problems.

(B) Advising CSA on procedures and programs which will promote State agency participation in carrying out the aims and objectives of the Economic Opportunity Act.

(C) Developing an Annual Report to the Director of CSA on the status and impact of Federal and State programs and services affecting low-income individuals within the State.

(c) *Measurable goals and activities in the Work Progam.* Goals and activities appearing in the applicant's work program must be stated in terms which are clearly measurable and must include the quantity as well as the quality and character of the improvements to be achieved.

§ 1061.90-6 Application process.

(a) *Funding offices.* The responsibility for application review, grant approval, and monitoring of grants funded under Section 231 lies with the appropriate CSA Regional Office.

(b) *Application requirements.* (1) Sixty days prior to the submission of an application for funds to CSA, an applicant selected by the Governor must:

(i) Submit eligibility documents to CSA as required in § 1061.90-4(b); and

(ii) Notify the state clearinghouse and the area clearinghouses (if appropriate) of its intent to apply for funds. (See § 1067.10 of this chapter for detailed instructions.)

(2) Ninety days before the expected funding date or, for refundings, ninety days before the end of the grantee's program year, the applicant/grantee must submit to the appropriate CSA Regional Office a formal grant application.

(3) The following documents must be submitted as part of the formal funding request:

(i) SF-424, Federal Assistance (including all comments received from clearinghouses)

(ii) CSA Form 419, Summary of Work Programs and Budget

(iii) CSA Form 515, Grantee Budget Information (pages 1 and 2) (See OMB Circular A-102.)

(4) If delegating programs the following additional documents must be submitted as part of the formal funding request:

(i) CSA Form 85, Administering Agency Funding Estimate

(ii) CSA Form 87, Delegate Agency Basic Information

(iii) CAP Form 11, Assurance of Compliance with Civil Rights Act.

§ 1061.90-7 Post-funding requirements.

Grantees receiving funds under Section 231 must comply with all CSA rules applicable to 231 grants. See § 1067.50 of this chapter for a listing of all such rules.

[FR Doc. 80-15978 Filed 5-23-80; 8:45 am]

BILLING CODE 6315-01-M

45 CFR Part 1070

Grantee Public Meetings and Hearings

AGENCY: Community Services Administration.

ACTION: Proposed Amendment to a rule.

SUMMARY: CSA is filing an amendment to its rule governing grantee public meetings and hearings. This amendment requires governing boards of nongovernmental Community Action Agencies to annually set aside one of their regularly scheduled meetings for the sole purposes of providing information to the community on the agency's salary schedule, the funds under its control and to adopt a budget for these funds. This amendment is one step in assuring compliance with the legislative requirements for grantee fiscal accountability and public access to information, records and books.

DATES: CSA welcomes comments on this rule. Comments received prior to July 28, 1980, will be considered in drafting the final amending language. Please address all comments to: Ms. Jacqueline G. Lemire, Community Services Administration, 1200 19th Street, N.W., Washington, D.C. 20206, Telephone (202) 254-5047, Teletypewriter (202) 254-6218.

FOR FURTHER INFORMATION CONTACT: Ms. Jacqueline G. Lemire, Community Services Administration 1200 19th Street, N.W., Washington, D.C. 20506, Telephone (202) 254-5047, Teletypewriter (202) 254-6218.

SUPPLEMENTARY INFORMATION:

Significance of Regulations

CSA has determined that under its criteria implementing Executive Order 12044 this is a significant change to a rule.

Through its legislatively mandated powers under Section 211(e) of the Economic Opportunity Act as amended, the governing board of a CAA is ultimately responsible for determining fiscal policies and approving overall program plans and priorities for the community action program in toto—that is whether projects are funded under Title II of the EOA or financial assistance is provided by other sources both private and public.

In carrying out it's responsibilities under the EOA to insure grantee fiscal responsibility and accountability, CSA has had reason to be concerned about whether CAA governing boards are carrying out their responsibilities for fiscal control of *all* community action program funds.

CSA also is concerned that the right of the community to information on the budget and activities of the entire community action program (not only that portion funded by CSA) is not always guaranteed. Section 213(a) speaks to this right to information. It requires that each CAA provide reasonable public access to information and to books and records of the CAA or other agencies engaged in program activities or operations involving the use of funds for which it is responsible. CSA has concluded that providing "reasonable public access" should not be defined as a merely passive act but that affirmative steps should be taken by CAA's to assure that the public has that information. In order to insure that there is control by the governing board of all CAA funds and that the total budget be open to public scrutiny, CSA is amending its policy on grantee public meetings to require that annually the board hold a public meeting whose sole purposes are (1) to provide the community the salary schedule of the agency and a comprehensive financial statement covering all assets, liabilities and summaries of revenue for all funds under control of the CAA, and (2) to adopt a detailed budget for such funds where appropriate.

(Sec. 602, 78 Stat. 530; 42 U.S.C. 2942)

Robert S. Landmann

Acting Director.

45 CFR 1070.2-3(a) is proposed to be amended by adding the following new subparagraph (3):

§ 1070.2-3 [Amended]

(a) * * *

(3) Annually, each nongovernmental CAA will set aside one of its regularly scheduled public meetings for the sole purposes of providing to the community the salary schedule of the CAA and how comparability was established, a comprehensive financial statement covering all assets, liabilities and summaries of revenue for all funds (regardless of source) under control of the CAA, providing information to the community on the uses to which these revenues have been consigned, and/or adopting a detailed budget for such funds.

* * * * *

[FR Doc. 80-16037 Filed 5-23-80; 8:45 am]

BILLING CODE 6315-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 33 and 94

[CGD 79-072]

Stowage of Lifeboats and Liferafts

AGENCY: Coast Guard, DOT.

ACTION: Supplemental Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard proposed to amend its regulations pertaining to the storage of lifeboats and liferafts for all inspected vessels having widely separated accommodation or working spaces. This document gives notice of additions to the proposal that have been made since the notice of proposed rulemaking was published and extends the comment period. The additions are based upon comments received in response to the original notice. The main additions are the inclusion of manned seagoing barges and Great Lakes vessels into the proposal.

DATES: Comments must be received on or before July 11, 1980.

ADDRESSES: Comments should be submitted to Commandant (G-CMC/TP24), U.S. Coast Guard Headquarters, Washington, D.C. 20593. Comments will be available for inspection or copying from 7:00 a.m. to 5:00 p.m., Monday through Thursday, at the Marine Safety Council (G-CMC/TP24), Room 2418, 2100 2nd St., SW., Washington, D.C. 202-426-1477.

The proposal has been evaluated in accordance with DOT "Regulatory Policies and Procedures," 44 FR 11033 (February 26, 1979). A draft regulation evaluation and the environmental impact assessment will be available for examination at the Marine Safety Council (G-CMC/TP24), Room 2418, U.S. Coast Guard Headquarters, 2100 2nd St., SW., Washington, D.C. 20593, 202-426-1477.

FOR FURTHER INFORMATION CONTACT: Lieutenant Daniel J. Zedan (G-MVI-2/

TP24), Room 2612, U.S. Coast Guard Headquarters, Washington, D.C., 202-426-2190.

SUPPLEMENTARY INFORMATION: Four comments have been received on the notice of proposed rulemaking of December 3, 1979 (44 FR 69312). These comments are available for examination at the Coast Guard, Marine Safety Council located at the above address. The public is invited to participate in this proposed rulemaking by submitting written views, data, or arguments. Each person submitting a comment should include the name and address, identify this notice (CGD 79-072) and the specific section of the proposal to which the comment applies, and give the reasons for the comment. If an acknowledgment is desired, a stamped, addressed postcard should be enclosed. The proposal may be changed in view of the comments received. All comments received will be considered before final action is taken on this proposal. No public hearing is planned, but one will be held at a time and place to be set in a later notice in the Federal Register if requested in writing by anyone raising a genuine issue.

Draft Information

The principal persons involved in drafting this supplemental notice of proposed rulemaking are: Lieutenant Daniel J. Zedan, Project Manager, Office of Merchant Marine Safety, and Michael N. Mervin, Project Attorney, Office of Chief Counsel.

Issues Raised by the Notice of Proposed Rulemaking

Among the issues and concerns raised in comments to the notice of proposed rulemaking are the following:

1. A clarification of the capacity each raft must accommodate.
2. A clarification of the term "widely separated accommodation or working spaces."
3. Whether manned seagoing barges should be included in the proposed amendments.
4. Whether present Great Lakes regulations should be reworded to read the same as the other proposed amendments.

Discussion of Comments and Additional Proposed Rules

One of the comments requested a clarification of the aggregate capacity requirement for the liferafts. The question was whether the regulation referred to at least one-half of the total number of persons aboard the vessel or of just the normal number of persons working or living in the area. The intent of the regulation is to require sufficient capacity to accommodate 50% of the total number of people aboard the vessel, not just the area, to ensure sufficient lifesaving equipment in the event the vessel breaks in two as in the case of the M/V Chester A. Poling. Therefore, the proposal remains unchanged.

Two Comments requested a clarification of the term "widely separated accommodation or working spaces" with one of them recommending that a definition be placed in the regulation. Because this is not a new term and has been used for years, no specific definition in this proposal is necessary. As far as clarifying its meaning, due to the design differences in each vessel, no set distance for determining what is or is not widely separated has ever been made. This has always been left to the discretion of the local OCMI. Accommodation spaces are those spaces where crewmembers eat, sleep, spend their recreation time, etc. and usually include, but are not limited to, crew quarters, recreation rooms, library, mess hall, etc. Working spaces are those spaces where crewmembers usually stand their watches. Examples usually include, but are not limited to, engine rooms, machinery shops, wheelhouse or bridge, radio room, etc. Areas such as storerooms and lockers in the forecastle head normally do not qualify as working spaces; however, as with the determination of accommodation spaces, the designation of what is a working space is left to the discretion of the local OCMI.

Two errors were noted in the notice of proposed rulemaking which should be corrected. In paragraph 94.10-10 and 192.10-10, the word "spaced" is used instead of "separated". To insure uniformity, all proposed changes should read "widely separated accommodation or working spaces."

The additions proposed by the remaining two comments, and included in this supplemental notice of proposed rulemaking, include the following:

1. An amendment has been added to table 46 CFR 94.10-40 concerning Great Lakes vessels by changing the wording of footnote number three to read the same as that used in the other proposed amendments.
2. An amendment has been added to 46 CFR 33.05-20(c) concerning Great Lakes tankers by changing the wording of the paragraph to read the same as that used in the other proposed amendments.
3. An amendment has been added to 46 CFR 94.10-15 concerning seagoing barges by adding a new paragraph (c) to read the same as the wording used in the other proposed amendments.

The first two proposals are designed to eliminate the inconsistency which presently exists between what is required for deep sea vessels and that which is required for Great Lakes vessels. As written now, Great Lakes vessels over 300 gross tons having widely separated accommodation or working spaces need only have two inflatable liferafts for the entire vessel with stowage location being left to the satisfaction of the OCMI. This requirement varies greatly with the present requirement for vessels on ocean and coastwise voyages and there appears to be no justification for the difference.

The third proposal is designed to require all manned seagoing barges, having widely separated accommodation or working spaces, to have the same degree of lifesaving protection as presently required for vessels in ocean and coastwide service. The Coast Guard is certificating many construction barges, i.e. derrick, pipe lay, and offshore oil industry, many of which carry as many as 500 persons. Under existing regulations, these vessels present a unique problem due to their configuration, and in many instances a majority of the lifesaving equipment has been placed in areas where it will not interfere with the vessels operation, but away from living or working areas. This could result in a large portion of the emergency equipment being lost in the event of an accident, i.e., helicopter crash or major fire. The proposed amendment would correct this problem.

In accordance with the foregoing, the following additions to the notice of proposed rulemaking of December 3, 1979 are proposed:

PART 33—LIFESAVING EQUIPMENT

1. By amending § 33.05-20(c) by deleting the last two sentences and replacing them with the following sentence:

§ 33.05-20 [Amended]

* * * Those tankships that have widely separated accommodation or working spaces must have at least one liferaft in each such location.

PART 94—LIFESAVING EQUIPMENT

2. By adding a new paragraph (c) to § 94.10-15 to read as follows:

§ 94.10-15 Requirements for seagoing barges in ocean or coastwise service.

* * * * *

(c) All manned seagoing barges of 100 gross tons and over in ocean or coastwide service, having widely separated accommodation or working spaces, must have at least one liferaft, of

sufficient aggregate capacity to accommodate at least 50 percent of the persons on board, in each such location.

§ 94.10-40 [Amended]

3. In § 94.10–40, footnote three to Table 94.10–40(a) is revised to read as follows:

[3] Every vessel of 300 gross tons and over, having widely separated accommodation or working spaces, must have at least one liferaft, of sufficient aggregate capacity to accommodate at least 50 percent of the persons on board, in each such location.

(46 U.S.C. 391a, 481; 49 U.S.C. 1655(b); 49 CFR 1.46(b) and (n)(4))

Dated: May 20, 1980.

W. D. Markle, Jr.,

Captain, U.S. Coast Guard, Acting Chief, Office of Merchant Marine Safety.

[FR Doc 80-16031 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-14-M

FEDERAL MARITIME COMMISSION

46 CFR Part 522

[General Order 24; Docket No. 80-32]

Exemption of Leases or Arrangements Solely Involving Terminal Facilities Located in Foreign Countries

AGENCY: Federal Maritime Commission.

ACTION: Proposed rulemaking.

SUMMARY: Exemption from the filing requirements of section 15 of the Shipping Act, 1916, for leases or arrangements solely involving terminal facilities located in foreign countries.

DATE: Comments due on or before July 28, 1980.

ADDRESS: Comments (Original and 15 copies) and Inquiries to: Secretary, Federal Maritime Commission, 1100 L Street NW., Washington, D.C. 20573 (202) 523–5725.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Federal Maritime Commission is considering a rule to exempt leases or arrangements solely involving terminal facilities located in foreign countries from the filing requirements of section 15 of the Shipping Act, 1916 (46 U.S.C. 814).

In Docket 79–18, *Exemption from the Provisions of the Shipping Act, 1916, and the Intercoastal Shipping Act, 1933,* public comments and suggestions were requesting concerning possible activities that could be exempted from present regulatory requirements imposed by the Shipping Act, 1916, and the Commission's Rules. From the comments submitted, it appears that leases or arrangements solely involving terminal facilities in foreign countries could be exempted without impairing the Commission's regulatory effectiveness or creating conditions which were unjustly discriminatory or detrimental to the commerce of the United States. Comments received in Docket 79–18 will be made a part of this proceeding and will not need to be refiled. Commentators are requested to address whether in their view the proposed exemption will substantially impair effective regulation by the Federal Maritime Commission or significantly affect the overall design of regulation contemplated by the Shipping Act, 1916.

Therefore, pursuant to sections 15, 35 and 43 of the Shipping Act, 1916 (46 U.S.C. 814, 833a, and 841a) and section 4 of the Administrative Procedure Act (5 U.S.C. 533), the Commission proposes to revise, 46 CFR Part 522 by the addition of a new § 522.9 as follows:

§ 522.9 Exemption of leases or arrangements solely involving foreign terminal facilities.

(a) *Exemption.* To the extent that the Commission has jurisdiction over this authority, leases or arrangements solely involving foreign terminal facilities are exempt from the filing and approval requirements of section 15 of the Shipping Act, 1916.

(b) *Optional Section 15 Compliance.* Notwithstanding paragraph (a) of this section, persons which desire Commission approval of a foreign terminal agreement solely involving foreign terminal facilities may file the agreement with the Commission for section 15 determination and approval in accordance with ordinary procedures.

(Secs. 4, 15, 35, 43; (5 U.S.C. 533, 46 U.S.C. 814, 833a, 841a))

By the Commission.

Francis C. Hurney,

Secretary.

[FR Doc 80-15995 Filed 5-23-80; 8:45 am]

BILLING CODE 6730-01-M

46 CFR Part 524

[General Order 23; Docket No. 80-34]

Exemption of Nonexclusive Transshipment Agreements From Section 15 Approval Requirements

AGENCY: Federal Maritime Commission.

ACTION: Proposed Rulemaking.

SUMMARY: Nonexclusive container and/or equipment interchange agreements would be exempted from the apporval requirements of section 15 of the Shipping Act, 1916.

DATE: Comments (original and fifteen copies) due on or before July 28, 1980.

ADDRESS: Address comments and inquiries to: Secretary, Federal Maritime Commission, 1100 L Street, N.W., Room 11101, Washington, D.C. 20573, (202) 523–5705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Federal Maritime Commission is considering the adoption of a rule to exempt agreements between ocean carriers involving the nonexclusive interchange of empty containers, chassis, barges and related equipment from the prior approval requirements of section 15 of the Shipping Act, 1916 (46 U.S.C. 814).

The Commission recently requested public comments and suggestions relating to areas of activity under Commission regulation that could be exempted from the approval requirements of section 15.* These comments indicated that equipment interchage agreements was one Shipping Act activity which could reasonably be exempted from regulation under the standards articulated in section 35 of the Shipping Act, 1916 (46 CFR 833a). Comments received in Docket 79–18 will be made a part of this proceeding and need not be refiled. Commentators are requested to address whether in their view the proposed exemption will substantially impair effective regulation by the Federal Maritime Commission or significantly affect the overall design of regulation contemplated by the Shipping Act, 1916.

Nonexclusive equipment interchange agreements generally comprise three categories, *i.e.,* (1) container, chassis and related equipment interchange agreements; (2) agreements involving the management of the equipment as well as the exchange of containers, chassis and related equipment; and (3) agreements covering only the repair and maintenance of containers, chassis and related equipment.

While LASH and SEABEE barges are not ordinarily included in these categories, these barges function in a manner similar to containers and it is proposed that agreements involving the nonexclusive interchange of such barges also be included in the exemption. Therefore, a fourth category specifically relating to agreements involving the nonexclusive interchange of LASH and SEABEE barges has been added to the above categories

This exemption should not substantially impair effective Commission regulation of common

* Docket No 79–18 *Exemption from the Provisions of the Shipping Act, 1916, and the Intercoastal Shipping Act, 1933.*

carrier practices, result in unjust discrimination or be detrimental to commerce, provided that such agreements are filed for information purposes in the manner proscribed below.

Therefore, pursuant to sections 15, 35 and 43 of the Shipping Act, 1916 (46 U.S.C. 814, 833a, and 841a), and section 4 of the Administration Procedure Act (5 U.S.C. 553), the Commission proposes to revise 46 CFR Part 524 by changing its title, renumbering and recaptioning existing §§ 524.2 through 524.6 as § 524.2, making nonsubstantive revisions in present §§ 524.5 and 6 to conform with proposed §§ 524.3 (d) and (e), and adopting a new § 524.3. The new material would read as follows:

PART 524: EXEMPTION OF CERTAIN AGREEMENTS FROM THE APPROVAL REQUIREMENTS OF SECTION 15, SHIPPING ACT, 1916

§ 524.3 Nonexclusive equipment interchange agreements.

(a) *Definition.* A Nonexclusive Equipment Interchange Agreement for the purpose of this Part is an agreement between two or more carriers for the mutual exchange of containers, chassis, SEABEE and LASH barges, and other related equipment; which agreement does not prohibit either carrier from entering into similar agreements with other carriers.

(b) *Conditions to be met.* Nonexclusive Equipment Interchange Agreements are hereby exempted from the filing requirements of section 15 provided they conform with the language and format set forth in 524.3(c) and provided that two copies are filed with the Commission 30 days prior to implementation for information, but not for approval.

(c) *Format.* Nonexclusive Equipment Interchange Agreements shall adhere to the following form:

Nonexclusive Equipment Interchange Agreement No. ———
Participating Carriers: ———

The parties to this agreement agree to nonexclusive:

(1) interchange empty containers, chassis, empty barges, and related equipment; to transport the equipment of the other as the circumstances and conditions of these trades may require and permit; said interchange or transport to be subject to mutually acceptable Agent to record movement of and to dispatch their containers, barges and/or related equipment only; [1]

(2) provisions covering payment for use of the equipment, if any;

(3) provisions relating to the management of equipment use and position of empty equipment;

(4) provisions covering damage to equipment and liability arising out of the use of the equipment;

(5) provisions covering the arbitration of any disputes;

(6) provisions covering the termination of the agreement.[2]

Date at ——— this ——— day of ———, 19—.
By: ———
By: ———

(d) *Optional section 15 approval.* Notwithstanding the provisions of this section, persons which desire approval of equipment interchange agreements may continue to submit such agreements with the Commission for section 15 determination in accordance with ordinary filing procedures.

(e) *Termination of section 15 approval.* Interchange agreements which have received section 15 approval may be converted to exempt status agreements upon submission of a petition for termination and exemption which demonstrates that the agreement in questions meets the requirements of this section.

By the Commission.
Francis C. Hurney,
Secretary.

[FR Doc. 80-15993 Filed 5-23-80; 8:45 am]
BILLING CODE 6730-01-M

[1] Language of paragraph 1 is mandatory.

[2] Language of paragraphs 2 thru 6 may vary with each agreement.

46 CFR Part 536

[General Order 13 Revised; Docket No. 80-33]

Exemption of Tariff Matter Covering the Movement of Cargo Between Foreign Countries Either Transshipped From One Water Carrier to Another at U.S. Ports or Transported Overland Through the United States

AGENCY: Federal Maritime Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This rule is proposed to exempt from the filing requirements of section 18(b) of the Shipping Act, 1916, tariff matter covering the movement of cargo between foreign countries, either transshipped from one water carrier to another at U.S. ports or transported overland through the United States.

DATE: Comments due on or before July 28, 1980.

ADDRESS: Comments (original and 15 copies) to: Secretary, Federal Maritime Commission, 1100 L Street, NW., Room 11101, Washington, D.C. 20573.

FOR FURTHER INFORMATION CONTACT: Secretary, Federal Maritime Commission, 1100 L Street, NW., Room 11101, Washington, D.C. 20573, (202) 523-5725.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Federal Maritime Commission is considering the adoption of a rule as set forth below to exempt tariff matter covering the movement of cargo between foreign countries either transshipped from one water carrier to another at U.S. ports or transported overland through the United States from the filing requirements of section 18(b) of the Shipping Act, 1916.

The Commission in Docket 79-18, *Exemption from the Provisions of the Shipping Act, 1916, and the Intercoastal Shipping Act, 1933,* requested public comments and suggestions relating to the areas of activity under Commission regulation that could be given exemption from the filing requirements of the Shipping Act, 1916, without impairing the Commission's regulatory effectiveness. From the comments submitted, it has been determined that tariff matter covering the movement of cargo between foreign countries either transshipped from one water carrier to another or transported overland through the United States could be exempted without impairing the Commission's regulatory effectiveness. Additionally, there has been no showing that this exemption would be unjustly discriminatory or detrimental to the commerce of the United States. Comments received in Docket 79-18 will be made a part of this proceeding and need not be refiled. Commentators are requested to address whether in their view the proposed exemption will substantially impair effective regulation by the Federal Maritime Commission or significantly affect the overall design of regulation contemplated by the Shipping Act, 1916.

Therefore, pursuant to sections 18(b) and 35 of the Shipping Act, 1916 (46 U.S.C. 817 and 833a), and section 4 of the Administrative Procedure Act (5 U.S.C. 553), the Commission proposes to revise Part 536 by the addition of § 536.1(a)(7) as follows:

PART 536—PUBLISHING AND FILING TARIFFS BY COMMON CARRIERS IN THE FOREIGN COMMERCE OF THE UNITED STATES

§ 536.1 Exemptions and exclusions.

(a) The following services are exempt from the tariff filing requirements of the Act and the rules of this part:

(7) Transportation movements of cargo between foreign countries either transshipped from one water carrier to another at United States ports or transported overland through the United States via any mode or routing.

By the Commission.

Francis C. Hurney,

Secretary.

[FR Doc. 80-15996 Filed 5-23-80; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[BC Docket No. 80-190; RM-3630; FCC 80-261]

Amending FCC Form 324 Annual Financial Report of Broadcast Stations

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Action taken herein institutes a rulemaking proceeding which seeks to revise the broadcast financial reporting requirements. It also asks for comment on a petition by the National Association of Broadcasters which seeks to delete such requirements. The proposed new reporting requirements would improve the quality of the data and omit certain kinds of data that are no longer necessary or can be obtained from other reports filed by licensees.

DATES: Comments must be received on or before September 15, 1980, and reply comments must be received on or before November 14, 1980.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Alan Stillwell, Broadcast Bureau, (202) 632-6302.

SUPPLEMENTARY INFORMATION:

In the matter of amendment of Form 324 Annual Financial Report of Broadcast Stations.

Adopted: April 24, 1980.

Released: May 14, 1980.

By the Commission: Commissioner Lee absent; Commissioner Quello concurring in the result.

Notice is hereby given of the institution of a rule making proceeding looking toward the revision of FCC Form 324, the Annual Financial Report of Networks and Licensees of Broadcast Stations.[1] In recent years the Commission has been evaluating the current reporting requirements in light of our current need for financial data. It has been 18 years since the Commission last completed an overall review of its reporting requirements.[2] This *Notice* results from the Commission's consideration of this matter and our desire to revisit the question of financial reporting requirements after almost two decades.

2. The Commission also has before it a petition for rule making from the National Association of Broadcasters seeking to delete Section 73.3611 of the Commission's Rules and Regulations (47 CFR § 73.3611) which requires all commercially operated broadcast stations to file an Annual Financial Report. The NAB petition also suggests, as an alternative, that the Commission reevaluate the necessity for the requirement that financial reports be filed each year. This petition has been accepted and assigned a rule making number (RM-3630). However, since it closely relates to the issues raised herein, we will incorporate the matter into this proceeding. While parties may comment on any aspect of the petition, we have indicated herein our strong preference to continue the collection of financial information for policy making proceedings. Further, we have specifically raised the question herein at paragraph 36 concerning the necessity to continue collecting Form 324 data on an annual or at some less frequent interval.

3. This proceeding will focus on the specific reporting requirements necessary to meet our needs for financial data and on the potential costs to broadcast licensees of providing that data.

Background Information

4. Over the years the Commission has required that financial information be filed by applicants or licensees in two contexts. First, at the time a major application is filed (e.g., television license renewal application, application for construction permit for a new radio or television station, etc.,) the applicant must submit a showing of financial qualifications.[3] Such showings usually include a statement of the applicant's assets and liabilities and, in the case of construction permit applications, sources of funds, annual income, and expected costs of construction and operation.

5. Secondly, since 1938, the Commission has required each licensee to submit an annual financial report. The early forms were quite extensive and required very detailed financial data to be reported. Through the years, it is recognized that the Commission neither needed nor used such detailed information and accordingly the reports have been reduced to a relatively simple statement of the revenue and expense related to broadcasting, the number of persons employed by the station, and a statement of the cost of tangible property devoted to broadcasting.

6. This rule making focuses only upon the annual financial report that is now embodied in FCC Form 324 and its instruction. It does not address the question of what is required to establish that applicants are financially qualified.

7. Eighteen years have elapsed since the Commission last completed an overall review of its annual financial reporting requirements. Since that time, questions have been raised with increasing frequency about the adequacy of the data provided by the Form 324 to meet the Commission's increasing need for economic analysis of the broadcast industry and the potential economic effects of its regulations. For example, data from different stations are often not comparable because the current form and instructions allow considerable latitude for licensee judgment in allocating revenue and expense accounts to the various line items. Also, some have argued that the limited income statement structure of the report may not provide the right kind of data for some of the economic questions that arise in broadcast regulation.

8. As a result of the increasing concern for the usefulness of the data, the Commission, in 1977, issued a contract to T&E, Inc. (T&E), an independent research firm, to study the Commission's need for financial information and the industry's methods of accounting, and to recommend revisons to Form 324 in light of their findings.[4] Since all reporting requirements impose a burden on those who must respond, the Commission also asked that the contractor make every effort to assure that their recommended changes meet our information needs without imposing undue costs on licensees.

9. T&E recommended more comprehensive definitions and reporting

[1] § 73.3611 of the FCC rules and regulations requires the annual submission of FCC Form 324 by the licensee of each commercially-operated broadcast station.

[2] *Memorandum Opinion and Order* in Docket 13842, FCC 62-1328, 24 RR 1631 (1962).

[3] Such filings are not required for radio station renewals.

[4] The T&E, Inc. report is available in the Commission's library, Room 639, 1919 M St., N.W., Washington, D.C. Copies of the study can also be obtained from the Downtown Copying Center, 1730 K St., N.W., Washington, D.C. 20006. The study is too voluminous to release as part of this document but will be placed in the docket of this proceeding upon release of this Notice.

instructions for all line items, and expansion of the Form 324 to include a more detailed breakdown of expenses, and a balance sheet. These recommendations have been thoroughly reviewed by the staff and will be discussed in detail below. However, before we can review the recommended reporting requirements, we must address the need for financial data.

The Need for Financial Data

10. Over the past 42 years, the financial information collected annually from broadcast licensees has been used for a number of purposes. It has provided data for policy research in support of major rulemakings or legislation;[5] it has provided information to estimate the potential economic harm of grants of specific applications, as in UHF impact cases;[6] it has provided support for statements of financial qualifications in transfer and assignment of license cases; when summarized by markets and industry segments, it has provided a valuable picture of the structure and economic status of the industry over time;[7] and it has provided information in other matters where the financial condition of stations is of interest. we are also aware that the broadcast industry uses the information from the published reports, compiled from the current form for planning and evaluation purposes. In a similar context, the published data might also provide information needed by prospective entrants to the industry to guage the viability of opportunities for new stations.

11. All of these uses are important, but not all constitute justification for the Commission's collecting the data on an industry-wide basis. When financial information is needed for a specific case, for example, it could be gathered as part of the fact-finding process of that case. By collecting such data on a case-by-case basis, the Commission could specify its request to obtain that information which is most pertinent to each particular case. Also, while we support and encourage the use of the data by the industry for planning and investment decision making, we do not believe those uses provide sufficient justification to warrant our collection of data. A more appropriate approach to serve these purposes might be to let the industry itself specify and develop the information it needs.

12. Our need for the regular collection of financial data on an industry-wide basis stems from our need to make informed policy decisions. The major portion of the broadcast industry is composed of stations whose ability to provide service to the public and, indeed, viability depend on their success as a business venture. Many of our decisions affect the costs and revenues of the business either directly or indirectly. The greater our understanding of the economic structure of the industry and the greater our understanding of the economic effects of our decisions and the incentives they are likely to affect, the better we will be able to arrive at judgments that achieve the desired effect on service from the industry. Such understanding of the general economic trends and relationships within the commercial broadcasting industry must rely substantially upon analysis of economic data gathered from the industry.

13. In this respect, the data from the current form have been highly useful for some policy purposes and less useful for others. For example, the broadcast financial data have proved valuable for reassessing existing policies intended to foster the development of new stations, such as the special UHF-aural exception to the one-to-a-market rules.[8] They have also provided support in development of new policies to accomplish this same purpose that take advantage of changes in the state of the industry, such as the recent revision of our policy towards the financial qualifications of applicants for new television stations.[9] Additionally, the data have been useful in evaluating policies where there are questions concerning their economic impact on existing stations. Examples of proceedings that have addressed such questions are the Cable Economic Inquiry (Docket 21284) and the Canadian Pre-Release proceeding (Docket 20649).

14. When the focus of research has shifted to studies concerning the behavior of individual broadcast stations and markets, however, the financial data have not been as useful. This was demonstrated in a study of the viability of UHF stations in the top 100 markets prepared by R. E. Park under contract to the Commission.[10] This study found that the financial data were not very useful for predicting the economic performance of individual UHF stations, because of the variability in stations' reported data. Part of this variability may be due to the reports themselves, for example, the lack of detailed definitions.

15. We turn our attention now to the kind of data we should collect in order to meet our needs. One approach to this task would be to identify a number of different policy matters and then determine the data needed to support research on these matters. We recognize, however, that it is not possible to anticipate all of the forthcoming issues and policy matters that will require economic or financial analysis. In addition, the needs of a specific analysis or study often become well defined only after substantial initial investigation has been completed. Because of these limitations, we have chosen instead to focus our specification of need on the more general kinds of requirements that can be derived from the planned direction of our broadcast regulatory program for the foreseeable future.

16. We have, in recent years, begun to determine the extent to which our policy goals and objectives can be served by a system of regulation that relies on market forces rather than direct regulation of behavior.[11] Policy objectives under such a system would be effected through careful attention to market structure and competitive forces. The advantage of this approach is that there would be less need for government involvement in the day-to-day affairs of individual stations, thereby facilitating the removal of much of the burden of performance regulation from the industry. We desire to encourage the maximum number of economically viable broadcast entities and have initiated a number of rulemaking proceedings that look in this direction (e.g., 9 kHz channels for AM stations—BC Docket 79-164; changes in the rules governing assignment of FM channels—BC Docket 80-90) and are planning others (e.g., examining common ownership of AM and FM stations in the same market; reviewing rules relating to subscription television stations).

[5] Recently, for example, staff analysts of Congressional committees, in drafting legislation affecting the broadcast industry, have used the Form 324 data in drafting proposals. (See FCC 79-589, Mimeo No. 14735, September 28, 1979.) The data are also being used in a current rule making proceeding concerning the special exception to the one-to-a-market rules which provides for UHF-aural applications to be handled on a case-by-case basis (see BC Docket 79-233, FCC 79-537) and in research to support a rule making that will be initiated in the near future concerning common ownership of AM and FM stations located in the same market.

[6] See, for example, *Memorandum Opinion and Order*, BC Dockets 79-254 and 79-255, released October 16, 1979, which relied in part on financial reports in determining the need for a hearing.

[7] See the summarized financial data reports "TV Broadcast Financial Data—1978" (Mimeo No. 19540, July 30, 1979) and "AM and FM Broadcast Financial

[8] See footnote 6.

[9] See FCC 79-299, May 11, 1979.

[10] Park, R. E., "Projecting the Growth of Television Broadcasting: Implications for Spectrum Use," The Rand Corporation (Santa Monica, California, February, 1976).

[11] See, e.g., Notice of Inquiry and Proposed Rulemaking: Deregulation of Radio, BC Docket No. 79-219, 44 FR 57645.

17. The structural approach to regulation will require substantial information about the various economic relationships that operate at the station, market, and industry levels. For example, at the station level, an understanding of the factors affecting viability and ability to provide service is necessary to develop policies to encourage new entry and better service. At the market level, knowledge of competitive forces and their relative strengths is necessary to establish policies to foster competition. Industry level information is needed to understand trends in broadcasting and to gauge the effects of emerging alternatives to broadcast services on the industry. It is our intention through this proceeding to develop the means to obtain financial data relating to each of these levels of analysis.

The Framework for Development of Financial Reporting Policy

18. There are several important considerations underlying the development of financial reporting requirements. First, any information collected must be suited to our needs—in this case policy analysis and planning. The data should also provide reliable measures of the various economic factors associated with broadcast stations. And, finally, the data should be sufficiently comparable across individual stations and over time to permit its use in forming generalizations and determining trends.

19. Our experience with the current form suggests that it does not provide data that are commensurate with our needs in view of these considerations. For example, the current financial data are generally neither reliable in terms of what economic characteristic is measured by specific line items, nor are they consistent across different stations in the sense that the financial data are not allocated to the various line items in the same manner by different stations. We believe that these problems are principally due to inadequacies of the design of the form itself and are not the fault of stations that file the reports.

20. We are also concerned about the costs that financial reporting requirements impose upon individual stations. Any policy requiring stations to submit information to the Commission naturally carries with it certain costs that station licensees must bear. We continue to believe that the costs of data collection must be justified by need and that such costs should be limited to the minimum necessary to accomplish policy objectives.

21. Our first step in developing proposals for revising Form 324 was to consider the kind of financial data that would meet our needs. The two basic sources of financial data that are generally relied upon to characterize the financial performance and condition of a business enterprise are the earnings (income) statement and the statement of financial position (balance sheet). The earnings statement summarizes the revenue and expense transactions which occur during a specified period of time, usually one year, to show income or loss. The statement of financial position on the other hand, describes the company's assets, liabilities, and owner's equity as of a given date.[12] The two reports individually and together provide the basis for various measures of the progress and financial condition of the firm.

22. For policy research purposes, earnings data are essential in tracking the development and condition of both individual stations and the industry as a whole and in assessing licensees' reactions to our policy decisions or changes in market forces. The areas of policy research for which earnings statement data are most essential are those involving questions of station viability, and the ability of stations to provide service and the potential of markets to support additional broadcast entities.

23. Questions concerning these areas cannot be wholly answered through earnings data as the ultimate effect of any change in the economic and/or regulatory environment depends in large part on the reaction of investors to such a change. The decisions of investors are generally based on the expected rate of return on their capital and the level of risk associated with its obligation.[13] These two factors are frequently assessed by examining various measures of profitability and financial health that require balance sheet data. For example, one measure of profitability is the ratio of net income (after interest payments) to owner's equity.

24. There is, however, reason to question the reliability of measures constructed from balance sheet data as indicators of the investment potential of firms in general and broadcast stations in particular. A balance sheet lists items according to their book value rather than their market value, which is the more appropriate measure to consider in the context of investment analysis. In general, the two alternative systems of valuation yield equivalent figures only under unusual circumstances, such as at the actual time of the sale of a firm or particular assets.

25. Another problem that affects the balance sheets of broadcast stations is that when stations are sold, the selling price is typically much higher than the market value of the physical assets, program rights, and other factors that support the operation of the station. The difference is an amount to compensate the seller for the transfer of certain intangibles, in this case the station's license and established position in its market, which may allow the owner to earn income above that necessary to keep its assets employed in the operation of the station. Since a station license is an intangible, its current value generally would not be expected to appear on a station's balance sheet except when a station is sold. Over time, the value of broadcast licenses has grown steadily and continues to grow, reflecting the long term growth in demand for stations. Because license values change constantly and stations are sold at different times, the book value of two licesnes which are actually worth the same can be vastly different.[14]

26. Another major concern related to our need for data is whether to treat radio and television stations differently. We recognize that radio stations are generally much smaller and less complex operations than television stations. Because of this, separations between functional activities such as engineering, programming, and sales, might not be so well defined for radio stations as they are for television stations. For example, the owner/operator of a small radio station may serve as chief engineer in addition to his or her responsibilities as station manager. Disk jockeys may sell time when not on the air. Under these circumstances, detailed financial data, especially for expenses, could only be obtained by arbitrarily allocating expenses to the various line items. For this reason, such reports would be less comparable across different stations and, therefore, less useful for policy analysis. In addition, the burden of providing financial data may be relatively greater on radio stations because of their size.

[12] Owner's equity is that portion of the value of the firm which belongs to its owners free and clear of debt.

[13] The rate of return on capital is the amount of income earned per dollar invested.

[14] Consider a hypothetical case in which two similar VHF television stations operate in the same market. Suppose that both stations came on the air at the same time, many years ago, and that the original value of each of their licenses was $100,000. Suppose, now, that one of the stations was recently sold and the price of its license was established at $1,000,000 while the other station has never been sold and its license has never been reappraised. The difference between the recorded license values would therefore be $900,000 or a factor of 10.

27. On the other hand, the Commission is currently pursuing a number of policy directions with respect to radio which may increase the need for radio financial data, at least in the near term future. In particular, we will likely need radio data to support and track the effects of decisions on matters such as radio deregulation and to develop and evaluate policies and rules intended to increase opportunities for new stations.

28. Our tentative preference is to require radio and television stations to report the same amount of data. If we do not collect adequate radio data, we may not be able to answer many of the questions which will arise relating to decisions on radio deregulation. We encourage comment on all aspects of this matter. In particular, we would like information concerning the reasonableness of separating radio station expenses by functional category as described in paragraphs 47–50 below and the relative costs of providing this detailed data as opposed to a single figure for total expense.

Proposed Revisions to the Financial Reporting Requirements

29. Using the preceding analysis and the recommendations of the T&E, Inc. report, we have established a set of proposed revisions to the Form 324 report. The proposed revisions provide for data which are generally similar in kind and quantity to those which are obtained through the current Form 324. There are, however a number of important changes designed to improve the quality of the data and to omit certain kinds of data that we do not consider necessary or that can be obtained from other reports licensees are required to submit. The most significant proposed revisions are to delete requirements for employment and tangible asset data and to restructure the income statement and clarify the definitions of its line items so as to conform with generally accepted accounting principles and accounting practices commonly employed in the industry. The complete proposed new Form 324 is attached as Appendix A; for comparison purposes the current form is attached as Appendix B.

30. We propose to eliminate collection of employment data, reported on Schedule 4 of the current form, because similar information is available from the Annual Employment Report (FCC Form 395) that all stations are required to file. We also considered an option suggested in the T&E report to expand the amount of employment data by adding separate categories for the technical, program, sales, and general and administrative functions. The employment schedule and associated instructions recommended by T&E, Inc. are shown in Appendix C. It is our opinion that this information would not be used on a regular basis for policy analysis, and, therefore, should not be collected.

31. With respect to balance sheet data, we considered three options: (1) to continue collection of tangible assets accounts as specified on the current form, (2) to require submission of standardized balance sheets as recommended in the T&E study, and (3) to eliminate collection of any balance sheet data. A copy of the balance sheet suggested by T&E is shown in Appendix D. We tentatively reject the first two choices on the basis that any balance sheet data we might collect would be of limited use in our policy research activities. The book value data carried on balance sheet accounts would not, in general, seem to be satisfactory for development of reliable measures of profitability. Moreover, a requirement for standardized balance sheets would likely impose significant new costs on licensees that do not appear to be justified by need and would be difficult to implement fairly since different sized stations are likely to use different types of accounting systems, no one of which is "correct." Also, some data on entry costs and the assets necessary to operate stations would still be available at the Commission as such information is required on applications for construction permits for new stations. Comparing income statement data to actual cost data may provide the best information on viability of broadcast stations.

32. We recognize that without well-defined balance sheet data that correspond to the same accounting period as the earnings data, our ability to perform important economic analyses may be somewhat diminished. Comments are therefore requested on the tentatively rejected proposals mentioned above as to their value as a basis for measures of profitability as well as on our preferred option of eliminating collection of balance sheet data. Other proposals that might provide alternative ways of obtaining such information are also invited. In particular, we are interested in information on factors which affect the flow of resources into and/or out of the industry. Comments are also requested on an approach which would obtain balance sheet data from all stations or a sample of stations at intervals less frequent than every year.

33. A number of new items have been proposed as additions to the income statement schedules. Most of the new items provide for more specific information under each of the major categories of expense and revenue on the current form and for adjustments to income. We are also proposing new or clarified definitions for many of the existing line items. The intent of these changes is to improve the quality of the data and, by providing clarification, to make the reporting task of the licensees easier. In this sense, we are attempting to structure the reporting format to more closely approximate an income statement according to the standards of generally accepted accounting practices and the practices of stations regarding the treatment of accounts as indicated by stations surveyed by T&E. This restructuring is expected to substantially improve the characteristics of the data for use in policy research studies.

34. There is one significant enlargement of the income summary schedule which is not related to data quality. For FM stations filing a combined report with a commonly owned AM station in the same market, we are proposing to revise the separate statement showing revenues attributable to the FM station. This statement would show somewhat more detail than the current separate FM statement and would enable us to better understand the position of FM in the industry. We believe such information to be important and appropriate to collect in light of the dramatic improvement in recent years in the competitive position of stations in the FM service.

35. Another alternative we wish to consider at this time concerns the separation of program expenses into local and non-local categories. While not included as part of the proposed form, this approach was recommended by T&E, and we wish to determine whether such data are available and whether it would be useful for policy analysis purposes. The specifications for reporting separate expenses for local and non-local programming as suggested by T&E are presented in Appendix D. We recognize that these data may be difficult to collect and may be of uncertain usefulness in policy analyses. Therefore, we are not presently including such data requests in the current form. However, comment is requested as to whether program expense data can be gathered according to these two categories and, if so, would it provide meaningful information for the analysis of the effects of changes in regulation or industry structure on local services.

36. We do not propose to change the frequency of filing of Form 324 from the current annual requirement. We believe it is desirable to continue to collect the data each year rather than shift to a plan which would interpose one or more time periods between reporting cycles. Under the latter approach, the most recent data would be two or more years old towards the end of the reporting cycle. The broadcast industry operates in an economic environment which is highly dynamic and, in light of developing technology, is likely to remain so in the future. Under these circumstances, data that are older will be considerably less useful for describing the current state of the industry and the various economic relationships within. Also, if only a sample is taken each year, then annual comparisons can be less readily made due to differences in the samples' composition. The preferred approach would provide the continuity of data flow that is required in studies that rely on time series data or data from the most recent prior business period. We invite discussion on this proposal and also request comments suggesting other alternative approaches that would require less frequent filings of financial data, for example every other year or once every five years. Suggested alternatives should also include discussion of any impact on the ability of the data so collected to serve the needs of policy analysis and evaluation.

37. We believe the needs of our policy studies make it advisable to require a survey of all stations. This would facilitate the construction of market and industry level data and would obviate many of the problems which are likely to arise with a more limited data base.

38. The proposed reporting period remains the calendar year. T&E found in its survey that about one-half of the respondents used the calendar year as their fiscal year. Further, T&E received very few comments opposing the use of the calendar year as the reporting year, even by those licensees who operate on a different fiscal year basis. We believe that the benefits to be gained from a uniform industry-wide reporting period outweigh the detriments. We encourage comments, pro and con, on this point.

39. While these proposals do indicate our preferred policy, comment is invited on all of the alternatives set forth above. Parties should feel free to propose and discuss alternative reporting requirements not set forth in this Notice. Parties are especially encouraged to submit information that will help the Commission to evaluate the cost of the proposals to its licenses and to submit any additional evidence that will help the Commission evaluate the merits of the proposals.

Detailed Instructions and Definitions

40. As we discussed above, many of the problems encountered in analyzing the data collected through FCC Form 324 are attributed to unclear and insufficient instructions and to imprecise line item definitions. T&E documented, for example, a wide variation in reporting practices used in completing the form. It is not surprising, therefore, that some of the data reported by some stations are not comparable with that reported by others. By no means do we intend to suggest that broadcasters purposely are misleading the Commission by using different accounting or reporting practices. Indeed, we recognize that the problem generally centers on the form itself. In the absence of sufficiently precise Commission guidance in defining how revenues and expenses should be reported, we cannot expect stations to follow a standard reporting approach.

41. Instructions, explanations and definitions for each line item are included with the proposed form in Appendix A. We seek comments on the appropriateness of these instructions in relation to the accounting procedures and definitions used by licensees in managing their stations' finances. We request comments on the clarity of the instructions and definitions, as presented, and on how well the proposed form is suited to provide data for the kinds of economic analysis that we have discussed above.

42. Several specific definitions and instructions have been significantly altered.[15] For ease of exposition, we will include discussion of these alterations in the following discussions of changes to the individual schedules.

Schedule of Revenues (Schedule 1)

43. The T&E analysis noted a number of deficiencies in the current FCC Form 324 schedule of revenues (Schedule 1). In particular, the present instructions for this schedule call for distinguishing the sale of time to national/regional advertisers as opposed to local advertisers, on the basis of the "type" of advertiser. That is, "national/regional time sales" denotes sales from the advertiser whose market is typically national or regional in scope; "local time sales" denotes sales from the advertiser whose market is typically local. For analytical purposes, this is desirable since the advertising decisions of companies engaged in nationwide business may be influenced by a different set of market conditions than those encountered by companies who market on a local scale. Since some stations are more dependent on local time sales than others, the effects of changes in national and local market conditions likely will have different effects across the industry. A definition based on type of advertiser would generate data useful in analyzing these effects. However, changes in the character of businesses engaged in broadcast advertising (e.g. growth of national retail chains and the regionalization of many service businesses such as banks and restaurants) are making this distinction less useful and the form much harder for licensees to complete. In this regard we note that T&E found, in their survey of accounting practices, that most (although not all) stations report national/regional and local time sales on the basis of the nature of the "agent" who sold the advertising time. Thus, for those stations, advertisements obtained for the station by its national or regional representative were counted in the national/regional time sales category, while advertisements obtained by the station's own sales persons were counted as local time sales.

44. Since the distinction between national/regional and local sales on the basis of type of advertiser no longer seems to fit business reality very well, and since industry accounting practice appears to support a distinction based on type of agent placing the advertising, we are proposing to amend our instructions and definitions to require the reporting of national/regional and local time sales on the basis of type of sales agent. We ask interested parties to comment on this proposal, especially in terms of its usefulness for industry analysts. We are interested in comments relating to the effect such a definitional change might have on the usefulness of the series of data reported in the past, and on the effects, if any, that the change might have for those in the industry who may rely on the separate time sales figures.

45. We are proposing another change in the revenue schedule that should improve reporting procedure. "Commissions to agencies and representatives" now is included in the revenue schedule as a deduction from revenue. T&E found in their survey that the industry treats advertising agency commissions in this way, but treats commissions to station representatives

[15] Many of the definitions and instructions that are being "changed" are not explicit in the current Form 324, but consist of various informal interpretations made by staff members in answer to questions raised by licensees over the years.

as a selling expense. Our proposal, following the recommendation of T&E, is to treat all commissions, including advertising agency commissions, as a part of selling expense. This appears appropriate from an analytical point of view. Furthermore, since licensees already report commissions, we are not asking for new data but only a shift of the data to another location in the form.[16] However, since the proposed change does appear to depart from industry practice somewhat, we ask for comments on this reporting change.

46. Another proposal would change the definition of "Broadcast Revenues Other Than From Sale of Station Time." Currently, the form requires this general item to be subdivided into components based on sale of station services and facilities to national and local advertisers. T&E found that broadcasters generally do not account for their non-time revenues in this way. We believe, therefore, that the current distinction is inappropriate. There are, however, sources of revenue for many broadcast stations that derive from station operation but not directly from the sale of time, for example, from the sale of programs or talent or the production of commercials. We propose to include these revenues in Schedule 1 under the same general heading, but with a different sub-division.[17] The new categories we propose are: "Revenue From the Provision of Materials, Facilities, Services, etc.," "Revenue From Subscription Television Operations," and "All Other Broadcast Revenue." The first category is essentially the combination of the current national and local categories. We are proposing to include subscription TV revenues in the second category as an interim step until this relatively new segment of the industry becomes more fully developed. The third category is added for completeness and would include, when appropriate, such revenue as donations.

47. We request comments on the reasonableness of this categorization of other revenues especially in terms of its reflection of actual business practice. We are particularly interested in discussions of whether or not the revenues and expenses of ancillary business operations should be included with the revenues and expenses of the broadcast operation. For example, should the revenues and expenses generated by the production of commercial advertisements be included on the FCC Form 324 when that production uses the staff, equipment and studio of the broadcast operation? Should the revenues and expenses of commercial advertisement production activity be reported if that activity is treated as a profit center separate from the station itself? We encourage discussion of similar questions for other business activities (program production, talent agency activity, etc.) as well.

48. Another proposed change in the revenue schedule relates to AM-FM stations that operate jointly and do not file separate reports. We are proposing that the FM portion of broadcast revenues be reported by source. The current form does not provide this kind of detail which, in our opinion, hampers analysis of the contribution of FM broadcasting to the advertising revenues of the industry. We seek comments on the ability of licensees to provide this kind of detail for jointly operated AM-FM stations.

49. It should be emphasized that the proposed form would allow the continued reporting of AM-FM joint operations in one report, but only if the two operations are so intertwined that the *operating expenses* cannot be effectively allocated to each station. This represents a change from the current practice of requiring a joint form unless all or virtually all of the FM time is sold separately. We ask for comments on the desirability of this modification in light of the growing self-sufficiency of the FM segment of the industry and in view of the need for better data about the economics of FM broadcasting. We encourage suggestions on how best to determine at what point AM-FM operations should report as separate entities, and on appropriate methods of allocating joint costs to each operation.

Schedule of Expenses (Schedule 2)

50. Regulatory activity can have significant direct effects on broadcasters' costs of doing business and, through these costs, on service to the public. Further, these regulatory effects may be reflected differently in different functions of station operation. Therefore, to form a base for analyses of regulatory effects, we consider it important to have an accurate picture of the relationship of the cost of each function to the total operating cost of the station. The present FCC Form 324 defines four functional categories: Technical, Programming, Selling and General and Administrative. We propose to retain those categories, but as indicated above we encourage comment on the option to separate program expenses into separate local and nonlocal categories. Further, we believe that the current Form 324 does not fully reflect all costs associated with the four functional categories, since many common costs are reported in the general and administrative category rather than being allocated to the individual functions.

51. Following our intention to improve the consistency of the data, we are proposing to change the expense schedule to require the allocation of many common categories of expense to each function. The current FCC Form 324 requires some allocation (basically salaries). The proposed form would require, in addition, the allocation of payroll taxes and fringe benefits, depreciation and amortization, travel and entertainment, communication expense, professional fees, parts and supplies, and facilities costs (rent, heat, light and power) to each function. These types of costs are often common to all functions but may be a greater or lesser part of each function.

52. We believe that requiring stations to allocate common costs among functional categories would lead to a higher degree of comparability between stations and to a more precise view of the contribution of each function to total cost. Evaluation and comparison of components of total expense may provide very useful explanations of variations in total expense that would otherwise be unexplained. However, we recognize that the allocation of such common costs may be quite arbitrary. We suggest (instructions, proposed Schedule 2) that time spent, space occupied or relative use are appropriate determinants of the amounts to be allocated to each function. We request comments on the appropriateness of such allocation for analytical use and on the validity of the suggested allocation methods.

53. We recognize, as discussed above, that many, if not most, small stations do not operate on a departmental basis and that allocation of operating costs to functional categories could be burdensome as well as, perhaps, arbitrary. For these reasons, we are proposing that stations with gross annual revenues less than $100,000, or $2,000 per week for stations operating less than a full year, report costs without allocation to function. We encourage comment on this proposal, especially as to the reasonableness of the $100,000 threshold.

54. We also propose some new line items in the expense schedule. We suggest that fringe benefits as well as facilities costs (rental, heat, light and power), communications expense, travel

[16] We will discuss, as a separate issue below in paragraph 55, the proposal to separate the "commission" expense item into local and national/regional categories.

[17] Non-operating revenues, such as interest income or sale of assets, are proposed for inclusion in schedule 3 and will be discussed below.

and entertainment, professional fees, parts supplies and materials, and promotional expenses all be reported as separate line items. These items generally have been reflected in the "Other Expense" line on the current form, the major element in the "Other General and Administrative Expense" category. As a result, these "Other" categories make up a significant portion of total expense and provide no useful content for analytical comparisons between stations or segments of the industry. For example, a recently purchased station may have high professional fees (legal and engineering) that, unless specifically identified, would diminish its comparability with other like stations. Since these are apparently items for which separate accounts are generally kept by the licensee, we do not perceive a significant reporting burden. However, we encourage comment on that point and on the potential usefulness to the Commission of the more detailed data.

55. Our proposed revisions contain several other changes in the expense schedule. The data reported for the line item "Talent Payroll," have been combined with the data reported as "All Other Programming Payroll." In addition, "Commissions" are reported as commissions to national/regional agents, representatives, and brokers and as commissions to local salespersons or agents. This distinction will be a useful reflection of the relative expense of making a sale through national/regional representatives versus the station's own salesforce. Also, we are proposing that the current line item "Allocated Costs of Management from Home Office or Affiliates" be divided into two line items: "Allocated Corporate Management Expenses" and "Allocated Corporate Overhead Expenses." This subdivision would allow analysts to take these two different allocations into account individually when, for example, examining the relative differences between group owned stations and non-group owned. The T&E survey found that these two types of allocations would not present a significant burden to those licensees who currently allocate common corporate costs.

Revenue/Expense Summary (Schedule 3)

56. We are proposing to add line items to the Revenue/Expense Summary schedule to reflect non-operating revenue and expense such as income from rent of land or facilities associated with the broadcast operation, interest income, gain or loss on sale of assets, etc. This information is crucial to the full picture of a station's financial situation in any one year and for comparison from year to year and station to station. The current instructions specify that some of these items, such as rental of broadcast related facilities for non-broadcast use, are to be reported on Schedule 1 as "Other Broadcast Revenue." Other items such as interest income, are not mentioned in the instructions but are nonetheless often reported as "Other Broadcast Revenue" because there is no other line available. Inclusion of either of these two kinds of data in total operating revenue can lead to misinformation when an analysis is made of a station's operating income or when comparisons are made between stations.

57. Our proposed Schedule 3 will also reflect the amount of federal, state and local income tax recorded for the reporting year. Inclusion of this important element of business "expense" is critical, we believe, to the accurate reflection of profit levels. We seek comments on the reasonableness of including these elements and ask for other suggested elements that may be needed for a full expense statement.

58. We are also proposing to redefine the principals to be included in the "Payments to Principals" item. The new definition embraces only expenditures resulting in payments to owners/stockholders and members of their immediate family and excludes payments to affiliated or parent companies that are reported as specific line items in Schedule 2. The "Payments to Principals" item is not intended to reflect the distribution of profit to the owners (e.g. dividends, owner's drawing account). The intent is to reflect those elements of expense (salaries, interest, rents, service fees) that are paid directly to the owners or close relatives. We believe that this information is necessary for thorough and accurate analysis of station economics.

Accounting Methods

59. In addition to the changes in content addressed above, we are also proposing that the financial data be reported on the basis of generally accepted accounting procedures. These are procedures that the accounting profession believes represent good accounting practice and that form the basis for financial accounting audits. We are persuaded that this requirement is appropriate for licensees' Annual Financial Reports. We need accurate data with reporting variability as limited as possible, without instituting a uniform system of accounts. Specific comment is requested as to any problems licensees may anticipate in adhering to generally accepted accounting procedures.

60. The generally accepted accounting procedures include provisions for disclosure statements as to how certain allocations of expenses are made and how depreciation and amortization are treated. The Commission is considering whether to require submission of such statements with the financial reports. The preferred option is to require licensees to retain such information and make it available to the Commission upon specific request. The items that appear to be most appropriate for reporting are the method of depreciation, the method of amortization, the method of allocation of corporate management and overhead costs, the method of allocation of expenses to functional categories, and the details of payments to principals. Comment is requested as to whether statements disclosing allocation practices are needed and, if so, the specific expense elements to be included. Information is needed regarding the cost to licensees of preparing disclosure statements, the analytic capabilities that might be gained through them, and how this information could be used to improve the comparability of data from different reporting entities.

Control and Verification

61. The current procedure used by the Commission staff to verify the data filed on Form 324 is limited to reviewing for internal consistency. Arithmetic checks are made on each form to make certain that the reported details sum to the reported totals. Large changes in revenues or expenses from one year to the next are confirmed with the licensee to make certain that a typographical error has not occurred. The Commission does not, however, audit the forms, nor does it require the licensee to submit an audited form certified by a Certified Public Accountant. We do not propose to change that policy. Our need for the data is basically analytical. And while that need requires consistency and reliability, it does not require, in our opinion, the burden of a CPA audit on the part of the licensee [18] or the burden on the Commission of hiring additional staff for auditing purposes.

62. We do propose, however, to expand our verification efforts by using the additional financial details collected through the new form and by expanding the number of financial items for which

[18] We are concerned here only with an audit of our report relative to the accounts of the licensee. We would not wish to discourage the valuable practice of audit of the licensee's own accounts.

we make year-to-year comparisons. We would expect to have an expanded program of follow-up with licensees to develop explanatory notes covering unusual items (such as unusually low salaries or unusually high G & A expenses) or unusual changes from year to year. In this regard, we call attention to the proposed requirement discussed above that licensees retain, and make available to the Commission upon request, the method and calculations used in allocating expenses to the various functional categories in Schedule 2.

63. The intent of such procedures is to increase the information content of the report not to question licensees' accounting practices. We believe that these expanded editing procedures, the detailed instructions accompanying the form, and the licensee's certification of the correctness of the information submitted, will provide adequate assurance that we will receive consistent and reliable data. We encourage comments upon our proposals for verification, especially in regard to their adequacy.

Supplemental Information

64. As indicated in our earlier discussion, it is our intention to collect on a regular basis only that data that are likely to be used on a regular basis or that are necessary to insure the reliability of the reports for interstation comparisons. On this basis, it is likely that special problems will arise from time to time that call for data that we do not have on hand. The Commission may, therefore, find it necessary to develop special surveys of licensees, asking for financial data not regularly reported on FCC Form 324, as revised. Such surveys may be industry-wide (as the 1972 special survey of "Other G & A Expenses") or directed to a smaller sample. In any case, we expect such surveys to be infrequent.

65. There are, however, some anticipated needs for recurring data not included on the proposed FCC Form 324, nor addressed in this proceeding. Subscription television stations have special revenue sources not available to conventional television stations. We are proposing that stations with STV operations include subscription revenue as a special line item under "Other Broadcast Revenue," at least for the time being. We plan a further proceeding, at a time when the STV segment of the industry is more fully developed, to determine a more appropriate delineation of financial data for STV operations.

66. Networks are another segment of the industry not addressed in this proceeding. The major program networks (ABC, CBS, MBS, NBC) now file a special financial report form (Form 324–A) with us. We propose no change in that form in this proceeding but plan to re-examine the validity and usefulness of that form in the near future. We note that Form 324 has for many years been titled "Annual Financial Report of Networks and Licensees of Broadcast Stations." We are proposing to change the title to "Annual Financial Report of Broadcast Stations" to better reflect the content.

Procedural Matters

67. Authority for the rule making and inquiry herein is contained in Sections 4(i), 303, and 308 of the Communications Act of 1934, as amended.

68. All interested persons are invited to file written comments on or before September 15, 1980, and reply comments on or before November 14, 1980. All relevant and timely comments and reply comments will be considered by the Commission. The Commission may take into account any other relevant information before it in addition to the comments invited by this Notice.

69. In addition, we plan to pretest the new form by asking a sample of stations to report their 1979 data on the new form and to respond to a questionnaire. The purpose of this pretest is two-fold: first to learn from those stations more about the actual problems encountered in providing the data, and second, to test the comparability and variability in reported data by using it in some ongoing economic studies. We anticipate that a report on the results of the pre-test will be made part of the record of this proceeding and would be available for interested parties to comment upon.[19]

70. In accordance with the provisions of Sections 1.419 of the Commission's Rules, an original and 5 copies of all comments, replies, pleadings, briefs or other documents filed in this proceeding shall be furnished to the Commission. Members of the public wishing to participate informally in this proceeding may submit a single copy of their comments, specifying the above-captioned docket number in the heading. Copies of all responses will be available for public inspection during regular business hours in the Commission's Docket Reference Room (Room 239) at its headquarters in Washington, D.C. (1919 "M" Street, N.W.)

71. For further information concerning this proceeding contact Alan Stillwell, (202) 632–6302. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, ex parte contacts presented to the Commission in proceedings such as this one will be disclosed in the public docket file. An ex parte contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentations requested by the Commission. If a member of the public does wish to comment on the merits of this proceeding in this matter, he or she should follow the Commission's procedures governing ex parte contacts in informal rulemakings. A summary of these procedures is available from the Commission's Consumer Assistance Office, FCC, Washington, D.C. 20554 (202) 632–7000.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[19] Individual station financial data would not be revealed in this report.

Appendix A: Proposed Form 324, Annual Financial Report of Broadcast Stations

General Instructions—FCC Form 324

Filing

—All licensees of commercial broadcast stations and all permittees whose commercial stations were operated during the year covered by this report must file Form 324. The licensee must file a separate report for each station except that: (1) An AM and FM station operated by the licensee in the same area may file one combined report if and only if the operations of the two stations are so interrelated as to make it impractical to report expenses separately for each station; (2) TV satellite stations that have no time sales of their own should combine their reports with that of the parent station.

—Stations operating non-commercially do not file.

—Licensees with broadcast revenue (Schedule 1, line 12) under $100,000 (or less than an average of $2,000 weekly) need not complete Schedule 2. The remainder of the report must be filed.

—Allocation of various expenses in Schedule 2 is required of all stations with revenues greater than $100,000.

—If the respondent's station was operated for part of the year under other ownership, the present and former licensees must file reports covering their respective periods of operation. Licensees are expected to file reports covering the period of the

year for which they actually operated. (Note: It is the responsibility of the present licensee to ensure that the former licensee has filed a report for his period of operation.)

Due Date

—One copy of the report must be completed for the calendar year and sent to the Federal Communications Commission, Policy Analysis Branch, Broadcast Bureau, Washington, D.C. 20554 by April 1 of the following year.
—Supplemental information, such as specification of Payments to Principals, shall be a size and durability comparable to, and securely fastened to, the report. Please place the respondent's call letters on the upper right-hand corner of each page and make reference to the pertinent schedule.
—Use only whole dollars; show no cents.
—If the licensee has *any* questions regarding Form 324 which these instructions do not answer, please contact the Policy Analysis Branch (phone (202) 632–6302).

BILLING CODE 6712-01-M

FCC Form 324

19___

ANNUAL FINANCIAL REPORT OF
BROADCAST STATIONS

BEFORE COMPLETING THIS REPORT, READ INSTRUCTIONS CAREFULLY

Mail one copy to: Federal Communications Commission
Policy Analysis Branch
Broadcast Bureau
Washington, D.C. 20554

1. Name of licensee: _____

2. Address: _____

_____

_____

3. Station Call Letters: _____

3a. (Previous call letters during reporting year, if any: _____)

4. Station Location: a) City _____
b) County _____
c) State _____

5. This report represents: *(Check one)*

- ☐ TV station
- ☐ TV Satellite
- ☐ Combined TV and Satellite
- ☐ AM station
- ☐ Combined AM and FM stations
- ☐ FM unaffiliated with AM in same area
- ☐ FM affiliated with AM in same area but reporting separately
- ☐ International station

6. If this report is for a TV station or satellite, check appropriate box:

☐ UHF ☐ VHF

7. Period covered (if other than full calendar year):

__/__/__ to __/__/__

8. Network Affiliations:

- ☐ (a) Not affiliated
- ☐ (b) Primary affiliation (ABC, CBS, NBC, or MBS, only): _____
- ☐ (c) Other affiliations: _____

_____

_____

BILLING CODE 6712-01-C

Instructions Applicable to Face Sheet

Line 1. Name of licensee as shown on FCC license.

Line 2. Mailing address of licensee, including street, box, or suite; city; state; and zip code.

Line 3. Licensed call letters.

Line 3a. Any other call letters, for this station *only*, which were previously in use during this reporting year.

Line 4. Location of reporting station.

Line 5. Check only one station type.

Line 6. Check only one appropriate box. For television only.

Line 7. Note beginning and end dates of which report covers if report covers other than full calendar year.

Line 8. Record all affiliations or check (a) Not affiliated if unaffiliated. List (b) Primary affiliation (only if ABC, CBS, NBC, or MBS) first and record all other affiliations in (c) Other affiliations.

BILLING CODE 6712-01-M

Schedule 1: Broadcast Revenue

Line				
1	A. SALE OF STATION TIME:			
2	(1) Networks - Major	$_____		
3	(2) Networks - Other	_____		
4	(3) Non-Network: National	_____		
5	(4) Non-Network: Local	_____		
6	TOTAL SALE OF STATION TIME		$_____	
7	B. OTHER OPERATING REVENUE;			
8	(1) Material, Facilities, Services, etc.	$_____		
9	(2) Revenue from Subscription Television Operations	_____		
10	(3) All other operating revenue	_____		
11	TOTAL - OTHER OPERATING REVENUE		$_____	
12	TOTAL OPERATING REVENUE		_____	
13	Less: Cash Discounts		(_____)	
14	BROADCAST REVENUE		$_____	
15	Total Value of Barter and Trade Out Transactions		$_____	

Schedule 1. Supplement - FM Revenue

16	TYPE OF REVENUE	
17	Time Sales - Major Networks	
18	Time Sales - Other Networks	
19	Non-Network: National	
20	Non-Network: Local	
21	Other Operating Revenue (Total)	
22	TOTAL	

BILLING CODE 6712-01-C

Proposed Instructions—Schedule 1

General. Barter and trade-out transactions should be reported as part of the total for all appropriate revenue categories. The contra expense (or asset) should be reported in the relevant expense or asset category. The FCC definition of barter/trade-out is included in the instructions for Schedule 1, Lines 15–21, Column (a).

Line 2.—Networks—Major. The gross amounts of revenue, before line or service charges, earned from major networks (ABC, NBC, CBS MBS only) as compensation for the time used by such networks for broadcasting network commercial programs on this station.

Amounts paid by the networks for circuit costs, royalties, and similar items of expenses which the networks furnish under contract are includable in the expense statement of the *network.* If the stations pay for these items, either directly or through networks as an offset against amount receivable, then such payments are includable in the expense statement of the station.

Note.—This line should *not* include revenue earned from the sale of network cooperative programs to non-network sponsors. The revenues earned in such a manner should be reported in Line 4 or Line 5.

Line 3.—Networks—Other. The same instructions are followed as in Line 2, but apply to revenue earned from networks other than those considered major. This line should *not* include revenue received from so-called "selling networks" (organizations which sell the station's time but do not provide it with any programs). Revenues earned in such a manner should be reported in Line 4 or Line 5.

Line 4.—Non-network: National. Revenue earned from time sales placed by agencies, representatives, and brokers who are of a national or regional status.

Note.—This revenue figure is after trade and/or special discounts but before cash discounts to advertisers and sponsors and before commissions of any kind.

Line 5.—Non-network: Local. Revenue earned from time sales through local agencies, representatives, brokers, and licensee's salespersons.

Note.—This revenue figure is after trade and special discounts but *before* cash discounts to advertisers and sponsors and before commissions of any kind.

Line 6.—Total sale of station time. The total of Lines 2 through 5.

Line 8.—Other operating revenues: Materials, facilities, services, etc. Include all broadcast operating revenues other than from time sales. Examples are revenues received from the supply of materials, facilities, services, and the use of talent on the station's payroll.

Note.—Do not include on lines 8, 9, or 10 revenue from non-operational transactions, such as interest income, gain (loss) on sale of assets, insurance claims, rental income of facilities owned by licensee but not part of the station operation.

Line 9.—Other operating revenue: Subscription television. Include the total revenue received from customers of subscription television service provided by this station.

Line 10.—Other operating revenue: All other. Include other operating revenue not shown in lines above (*e.g.* contributions).

Line 11.—Total—other operating revenue. Total, lines 8, 9, and 10.

Line 12.—Total operating revenue. Total, lines 6 and 11.

Line 13.—Cash discounts. Cash discounts taken by advertisers and others purchasing time, materials, facilities, or services, etc. from the licensee.

Line 14.—Broadcast revenue. Line 12 less line 13.

Barter Revenues

Line 15.—Total value of barter and trade out transactions. The total value of all barter and trade out transactions. This value must also be included as sales in the appropriate lines above.

The definition of barter used by the FCC (see release FCC–139) is:

"These [barter exchanges] are exchanges of a station's broadcast time for goods, programs, other media, or other services (in lieu of money).

These transactions may be made directly with the advertiser or with "third party agencies" acting in behalf of an advertiser . . .

Trade outs or barter transactions have value and should be reported in the Annual Financial Report (FCC Form 324). Spots exchanged for *program material* should be estimated at a fair value consistent with purchases of other program material of similar quality and quantity. Spots exchanged for *fixed assets* (such as furniture, automobiles, studio equipment, etc.), to which the station takes title or ownership for use in conducting business, should be estimated as the amount of cash which would have been paid for the asset, if the trade out were not available.

Spots exchanged *for merchandise* (such as radio sets, television sets, sporting equipment, theatre tickets, novelty items, items to be used as prizes, gifts, or give-aways), *for advertisements in other media* (such as newspapers, radio, television, transit ads, billboard, etc.), *for services* (such as hotels, travel, auto rentals, restaurants, etc.) are more difficult to value, but must be estimated for purposes of the financial report. Again, the amount of cash the station would have paid for the merchandise or service provides a reasonable basis for estimating the value.

In the Annual Financial Report, the value of traded time should be included as time sales when the spots are broadcast. The corresponding cost (estimated value) of the goods or services received should be treated in the report in the same manner as similar purchases for cash, *i.e.,* depreciated or expensed out."

Joint AM/FM Stations

Lines 17–22.—*FM revenues.* AM/FM operations filing jointly are to report total revenues for both AM and FM stations in Schedule 1, lines 1–14. Revenue figures applicable to the FM station alone are to be reported in lines 17–22 and correspond to the combined revenue lines as follows:

Line 17	Line 2
Line 18	Line 3
Line 19	Line 4
Line 20	Line 5
Line 21	Line 11
Line 22	Line 12

BILLING CODE 6712-01-M

Schedule 2. Broadcast Expenses

Functional Category

Line	Expense (a)	Tech (b)	Progr. (c)	Sell-ing (d)	Gen'l & Admin. (e)	Total (f)
1	Salaries & Wages					
2	Payroll Taxes & Fringe Ben.					
3	Travel & Ent.					
4	Communication Exp.					
5	Facility Exp.					
6	Parts & Supplies					
7	Professional Fees					
8	Depreciation					
9	Amortization					
10	PROGRAM-LOCAL & OTHER:	////	////	////	////	////
11	Rental & Amort of Film/Tapes	////		////	////	
12	Outside News Serv.	////		////	////	
13	Music License Fees	////		////	////	
14	Other Perf. & Prog. Rights	////		////	////	
15	SELLING:	////	////	////	////	////
16	Commissions - Local	////	////		////	
17	Commissions - National	////	////		////	
18	Promo & Adv. Exp.	////	////		////	
19	GEN'L & ADMIN.	////	////	////	////	////
20	Allocated Corp.Mgt.Exp.	////	////	////		
21	Allocated Corp.O.H.Exp.	////	////	////		
22	Other Expenses					
23	TOTAL					

BILLING CODE 6712-01-C

Proposed Instructions—Schedule 2

General Definitions

Functional Categories

1. *Column (b) Technical:* Technical Expenses.

This column includes, in the appropriate line item, all expenses related to the transmission of the station's signal, expenses incurred in maintaining the transmitter and the site, and expenses incurred in the studio and related areas which are considered to be of a technical nature. Salaries and fringe benefits paid to studio technicians, repair of broadcast equipment, etc., would be examples of such expenses.

2. *Column (c) Programming:* Program Expenses.

This column includes, in the appropriate line item, all expenditures related to programming. For example, charges for talent, directors, camera crews, program rights, and non-technical materials come under this category. Expenditures for studio equipment which is of a technical nature such as cameras, film chains, tape machines, ENC equipment, and control consoles are not included under this category but instead are to be placed under technical expenses.

3. *Column (d) Selling:* Selling Expenses.

All expenses related to selling, advertising, or promotion of the station. Examples would be commission to agencies or representatives and expenses related to salespersons' activities (phone, auto, etc.).

4. Column (e) General and Administrative: General and Administrative Expenses.

All expenses related to the management and administration of the station including overhead costs not allocated to other functions.

Note.—The allocation of expenses, where appropriate, should be based on a generally accepted cost accounting method. Time, space, and utilization are the major determinants of allocation.

Note.—For each line item, the total column is the sum of the preceeding line entires (b+c+d+e=f).

Line 1.—Salaries and wages. For each functional category, enter salary and wages, including overtime, vacation, termination pay, sick leave, and bonuses. These salaries should be allocated among functional categories and employee time spent in each category. Estimates are acceptable.

Line 2.—Payroll taxes and fringe benefits. All city, state and federal related payroll taxes as well as fringe benefits such as insurance, pension, etc. should be included here. The allocation among funtional categories should be performed in the same manner as Line 1.

Line 3.—Travel and entertainment. This should include travel, entertainment, and automobile related costs. Lease or rental of automobiles is to included. This is to be allocated by functional category on the basis of use, either actual or estimated.

Line 4.—Communication expenses. This includes telephone and telegraph, postage, membership dues and subscriptions, and courier services. Again, this is to be allocated by usage, either actual or estimated.

Line 5.—Facility expenses. Includes rent or lease expenses, utilities (heat, light, power), property related taxes (no other taxes), and maintenance and repair.

Line 6.—Parts and supplies. Expenses to be included vary by functional category. The bulk will be under Technical, such as tape, equipment parts, and supplies (excluding tubes), or under GE, such as general office supplies.

Line 7.—Professional fees. Fees paid to persons not on the station payroll for the provision of professional services.

Technical (Column b)—Technical consulting and engineering fees.

Local Programming (Column c)—talent fees; fees paid to other than staff for work such as announcers, consultants, actors, technicians, directors, etc. utilized in local programming.

Selling (Column d)—consultant expenses, etc.

G&A (Column e)—legal, auditing, consulting.

Line 8.—Depreciation. Varies by functional categories.

Technical: Include depreciation of studio, transmitter, and other technical equipment. For example, this would include cameras, mobile production facilities, tape machines, transmitters, towers, etc.

Programming: Include depreciation of non-technical non-electronic plant and equipment utilized in the programming functions. Examples are studio facilities, non-electronic equipment, etc.

Selling: Depreciation of assets utilized by sales and promotion department.

G&A: Depreciation of all assets which cannot be allocated to any of the above four functional categories.

Line 9.—Amortization. Varies by functional categories.

Technical: Amortization of leasehold and land improvements considered to be utilized for technical (transmitter, tower, etc.) purposes.

Programming: Amortization of those assets or portion thereof utilized in programming *EXCEPT* the value of programs held as assets. Includes studio.

Selling: Amortization of any assets utilized in selling.

G&A: All remaining of any assets utilized in selling. All remaining amortization costs *not* included in any of the four above *nor* to be included in Line 13, Rental and Amortization of Film and Tape *or* Line 18, Other Performance or Program Rights. An example is amortization of intangibles, such as good will.

Program (Local and Other)

Line 11.—Rental and amortization of film & tape. Include the rental cost of and the value of feature film and syndicated programming amortized during the report year. Do not include other film expenses such as raw stock, processing costs, shipping, audio tape, etc.

Line 12.—Outside news service. The cost of outside news services such as A.P. and U.P.I. Also include cost of news stringers.

Line 13.—Music license fees. Amounts paid to ASCAP, SESAC, BMI, and others.

Line 14.—Other performance and program rights. Cost and/or amortization of rights to broadcast programs not included in lines 13, 14 and 15. For example this line would include the amortization of rights to sports and special events.

Selling Expenses

Line 16.—Commissions—local. All commissions to agencies, reps, and brokers who are considered local. Include commissions paid to licensee's sales force.

Line 17.—Commissions—national. All commissions to agencies, reps, and brokers who are considered national and/or regional.

Line 18.—Promotion and advertising expenses. Include all trade and audience promotion and advertising expenses.

General and Administrative

Line 20.—Allocated corporate management expenses. Management expenses allocated by the home office or affiliate. Included would be the allocated cost of time spent by legal and accounting professionals for services rendered to the licensee, if not billed directly. Do not include interest expense.

Line 21.—Allocated corporate overhead expenses. Common overhead expenses allocated by home office to licensee. Include those expenses *not* in Line 22, Allocated Corporate Management Expense. For example, charges from the home office for use of a

central computer or billing service and allocated costs of maintaining the home office. Do not include allocated interest expense, which will be included in Schedule 3, Line 10.

Line 22.—Other expense. The accounts which go into each "other expense" line vary by functional (Technical, Local Program, Other Program, Selling, and G&A) category.

Technical: Include any expense appropriate to the technical function which has not yet been recorded.

Local programming: Include film expenses such as raw stock, processing and shipping, studio sets and props, program materials and facilities, records and transcriptions, audio tape, film expenses, line charges, co-op fees, outside origination costs, and other program expenses not elsewhere included in Schedule 2.

Selling: Include cost of rating services, audience research, and any other selling expense not elsewhere included in Schedule 2.

G&A: Include such costs as non-allocable insurance, charitable contributions, FCC license fees, corporate fees, miscellaneous state and local taxes (other than income) bad debt accounts, and other operating expenses which are neither allocable nor included in other line items. Be sure *not to include* non-operating expenses as mentioned in Schedule 3.

Schedule 3. Income

Line			
1	BROADCAST REVENUE		$_____
	OPERATING EXPENSE:		
2	Technical Expense	$_____	
3	Program Expense	_____	
4	Selling Expense	_____	
5	G&A	_____	
6	TOTAL OPERATING EXPENSE		$_____
7	OPERATING INCOME		$_____
	Other Income and Expense		
8	Non-Operating Revenue	$_____	
9	Interest Expense	(_____)	
10	All Other Non-Operating Expense	(_____)	
11	NET NON-OPERATING INCOME		$_____
12	INCOME BEFORE TAXES		_____
13	Federal, State and Local Income Tax		(_____)
14	NET INCOME		$_____
15	PAYMENTS TO PRINCIPALS Total Salaries, Interest, and Other Payments to Principals:		$_____

Proposed Instructions—Schedule 3

Line 1.—*Broadcast revenue.* Enter the total from Schedule 1, Line 14.

Line 2.—*Technical expense.* Schedule 2, Line 23(b).

Line 3.—*Program expense.* Schedule 2, Line 23(c).

Line 4.—*Selling expense.* Schedule 2, Line 23(d).

Line 5.—*General and administrative expense.* Schedule 2, Line 23(e).

Line 6.—*Total operating expense.* Schedule 2, Line 23(f). This should also equal the total of Lines 2 through 5 above.

Line 7.—*Operating income.* Line 1 less Line 6.

Line 8.—*Non-operating revenue.* Include all revenues accruing to the station which were not part of its broadcast operation. Examples are interest received, rent, and gain on investments or sale of assets.

Line 9.—*Interest expense.* All interest, either accrued by the station or allocated from the home office.

Line 10.—*All other non-operating expense.* Include all other expenses accruing to the station which were not part of its broadcast operation. For example, loss on investments or sale of assets.

Line 11.—*Net non-operating income.* Line 8 less Lines 9 and 10.

Line 12.—*Income before taxes.* Line 7 plus Line 11.

Line 13.—*Federal and State income tax.* The amount of income tax expense recorded for report year.

Line 14.—*Net income.* Line 12 less Line 13.

Line 15.—*Payments to principals.* Total salaries, interest and payments (exclusive of dividends or profit distributions) to principals or on behalf of principals that total more than $250 annually and are reported as part of expenses in Schedule 2. An example would be auto lease paid to principal of $50/month or $600/year. Include in an attachment a summary of the specific payments from which this figure is derived. State the number of principals receiving salary.

Person(s) in charge of correspondence regarding this report:

Name _____
Official Title _____
Address _____
Phone _____

Certification

(This report must be certified by licensee, or permittee, if an individual; by partner of licensee or permittee, if a partnership; by an officer of licensee or permittee, if a corporation or association; or by attorney of licensee or permittee in case of physical disability of licensee or permittee or his absence from the Continental United States.)

I certify that to the best of my knowledge, information, and belief, all statements contained in this report are true and correct and in accordance with generally accepted accounting principles where possible (or as note).* I also certify that the data regarding allocation methods and procedures are on file and available upon request.

Signed (licensee) _____
Title _____
Date _____

* Any person who willfully makes false statements on this form can be punished by fine or imprisonment. U.S. Code, Title 18, section 1001.

BILLING CODE 6712-01-M

Appendix B: Current (1979) Form 324, Annual Financial Report of Networks and Licensees of Broadcast Stations

NOT ROUTINELY AVAILABLE FOR PUBLIC INSPECTION

FORM APPROVED
GAO NO. B-180227 (R0001)

1979

ANNUAL FINANCIAL REPORT OF NETWORKS AND LICENSEES OF BROADCAST STATIONS

Mail one copy to the Federal Communications Commission, Policy Analysis Branch, Broadcast Bureau
Washington, D. C. 20554

BEFORE FILLING OUT THIS REPORT, SEE INSTRUCTIONS

1. _____ (NAME OF RESPONDENT)

2. _____ (STREET ADDRESS OR P.O. BOX NUMBER) (CITY) (STATE) (ZIP CODE)

3. Indicate the station(s) for which this report is submitted.

Current Call Letters _____ (OTHER CALL LETTERS OF STATION DURING REPORTING YEAR, IF ANY_____)

Location: _____ (CITY)

_____ (COUNTY)

_____ (STATE)

DO NOT REMOVE THE MAILING LABEL AFFIXED BELOW

RETURN COPY WITH MAILING LABEL TO THE FCC. RETAIN THIS COPY FOR YOUR FILES.

4. **Type of station reporting:** (CHECK ONE)

TV ☐ TV
TV ☐ TV Satellite
TV ☐ Combined TV and Satellite
AM ☐ AM
AF ☐ Combined AM and FM
FA ☐ FM affiliated with AM in same area
FM ☐ FM unaffiliated with AM in same area
☐ International

5. If this report does not cover the full **calendar** year, indicate the period covered: From: _____ To: _____

6. **Network affiliation(s) of station:** (PRIMARY FIRST) _____
(ABC, CBS, NBC, or MBS, only) (Network - Initials only)
OR CHECK IF NOT AFFILIATED ☐ (NO) _____

7. Licensee also owns the following stations for which separate reports are filed:

Call Letters	Type of Station*	Call Letters	Type of Station*

Indicate the type of station (See item 4 above)

Do not write below this line:

1. F P N C	2. A B	3.	4. O D S P R G
5.	6.	7.	8.

(All previous editions of this form are canceled.)

FCC Form 324
September 1979

1979

CALL LETTERS .....

SCHEDULE 1. BROADCAST REVENUES

LINE NO.	CLASS OF BROADCAST REVENUES (a)	MAKE ENTRIES IN THIS COLUMN FIRST (omit cents) (b)	USE THIS COLUMN FOR YOUR TOTALING ONLY (omit cents) (c)
		$	$
1	A. REVENUES FROM THE SALE OF STATION TIME:		
2	(1) Network		
3	Sale of station time to networks:		
4	Sale of station time to major networks, ABC, CBS, MBS, NBC (before line or service charges)		
5	Sale of station time to other networks (before line or service charges)		
6	Total (lines 4 + 5)		
7	(2) Non-network (after trade and special discounts but before cash discounts to advertisers and sponsors, and before commissions to agencies, representatives and brokers).		
8	Sale of station time to national and regional advertisers or sponsors		
9	Sale of station time to local advertisers or sponsors		
10	Total (lines 8 + 9)		
11	Total sale of station time (lines 6 + 10)		
12	B. BROADCAST REVENUES OTHER THAN FROM SALE OF STATION TIME (after deduction for trade discounts but before cash discounts and before commissions): (1) Revenues from separate charges made for programs, materials, facilities, and services supplied to advertisers or sponsors in connection with sale of station time:		
13	(a) to national and regional advertisers or sponsors		
14	(b) to local advertisers or sponsors		
15	(2) Other broadcast revenues		
16	Total broadcast revenues, other than from time sales (lines 13 + 14 + 15)		
17	C. TOTAL BROADCAST REVENUES (lines 11 + 16)		
18	(1) Less commissions to agencies, representatives, and brokers (but not to staff salesmen or employees) and less cash discounts		
19	D. NET BROADCAST REVENUES (lines 17 minus line 18)		
20	Report here the total value of trade outs and barter transactions. This value must also be included as sales in the appropriate lines above.		
21	If this is a report for a Joint AM-FM operation, indicate in lines 22, 23, 24 below the amounts, if any, of total broadcast revenues shown in the totals in line 19 above, which are applicable to the FM station ALONE.		
22	FM revenues from sale of station time (after discounts, commissions, etc.)		
23	FM revenues from providing functional music or other special services		
24	Other FM revenues		
25	Total (lines 22 + 23 + 24)		

1979 CALL LETTERS .....

SCHEDULE 2. BROADCAST EXPENSES

LINE NO.	CLASS OF BROADCAST EXPENSES (a)	MAKE ENTRIES IN THIS COLUMN FIRST (omit cents) (b)	USE THIS COLUMN FOR YOUR TOTALING ONLY (omit cents) (c)
1	TECHNICAL EXPENSES:	$	$
2	Technical payroll*		
3	All other technical expenses		
4	Total technical expenses		
5	PROGRAM EXPENSES:		
6	Payroll* for employees considered "talent"		
7	Payroll* for all other program employees		
8	Rental and amortization of film and tape		
9	Records and transcriptions		
10	Cost of outside news services		
11	Payments to talent other than reported in line (6)		
12	Music license fees		
13	Other performance and program rights		
14	All other program expenses		
15	Total program expenses		
16	SELLING EXPENSES:		
17	Selling payroll*		
18	All other selling expenses		
19	Total selling expenses		
20	GENERAL AND ADMINISTRATIVE EXPENSES:		
21	General and administrative payroll*		
22	Depreciation and amortization		
22a	Interest		
22b	Allocated costs of management from home office or affiliate(s)		
23	Other general and administrative expenses		
24	Total general and administrative expenses		
25	TOTAL BROADCAST EXPENSES (lines 4 + 15 + 19 + 24)		

Payroll includes salaries, wages, bonuses and commissions.

SCHEDULE 3. BROADCAST INCOME

LINE NO.		AMOUNT (omit cents)
		$
1	Broadcast revenues (from Schedule 1, line 19)	
2	Broadcast expenses (from Schedule 2, line 25)	
3	Broadcast operating income or (loss) (line 1 minus line 2)	
4	Show here the total of any amounts included in line 2 above which represent payments (salaries, commissions, management fees, rents, etc.) for services or materials supplied by the owners or stockholders, or any close relative of such persons or any affiliated company under common control (see page 3 of instructions).	
5	NOTE: If No such payments were made, check here ☐	

FCC Form 324 (Page 3)
September 1979

1979 CALL LETTERS .....

SCHEDULE 4. EMPLOYMENT

LINE NO.	
1	Indicate the number of employees in the workweek in which December 31 falls:
2	Full-Time _____ (17-24) Part-Time _____ (25-32) Total _____

(Do not count as "part-time" those employees who worked a full week but whose duties were divided between two or more stations of the license. Allocate those employees between the stations in accordance with instructions for Schedule 4 (pg. 4)).

SCHEDULE 5. TANGIBLE PROPERTY OWNED AND DEVOTED EXCLUSIVELY TO BROADCAST SERVICE BY THE RESPONDENT

LINE NO.	ITEM (a)	As of December 31		
		Total Cost (omit cents) (b)	Balance in accrued depreciation account (omit cents) (c)	Cost after depreciation (Col. (b) minus (c)) (omit cents) (d)
1	Land and land improvements and buildings			
2	Tower and antenna system			
3	Transmitter equipment			
4	All other property			
5	Total, all property (lines 1-4)			
		(41-48)	(49-56)	(57-64)

Person in charge of correspondence regarding this report:

NAME _____ OFFICIAL TITLE _____

ADDRESS *(Include ZIP Code)* _____

TELEPHONE NUMBER *(Include Area Code)* _____

CERTIFICATION

(This report must be certified by licensee or permittee, if an individual; by partner of licensee or permittee, if a partnership; by an officer of licensee or permittee, if a corporation or association; or by attorney of licensee or permittee in case of physical disability of licensee or permittee or his absence from the Continental United States.)

I certify that to the best of my knowledge, information, and belief, all statements contained in this report are true and correct.*

Signed ..... Date .....

Title .....

* *Any person who willfully makes false statements on this form can be punished by fine or imprisonment. U. S. Code, Title 18, Section 1001.*

FCC Form 324 (Page 4)
September 1979

INSTRUCTIONS FOR COMPLETION OF FCC FORM 324

SEPTEMBER 1979 EDITION

ANNUAL FINANCIAL REPORT OF NETWORKS AND LICENSEES OF BROADCAST STATIONS

GENERAL INSTRUCTIONS FOR BROADCAST STATIONS

1. Who must file reports? All licensees of commercial broadcast stations and all permittees whose commercial stations were operated during the year covered by this report. Stations operating on channels reserved for non-commercial use and non-commercial educational stations operating on commercial channels do not file.

2. What reports must be filed?

(a) One report shall be filed for each station of the licensee (whether AM, FM, TV, or other type of broadcast station) subject to the exceptions in (b) and (c) below.

(b) If the licensee operates an AM and an FM station in the same area, one combined report should be filed for these stations, except where all or virtually all of each station's time is separately priced and offered.

(c) If a TV station licensee also operates a TV satellite station (or stations), a separate report shall be filed for each satellite, except where the satellite station has no time sales of its own (in which case a combined report should be filed).

(d) Only one copy of report for each station need be filed.

3. What is the time period covered by the report? The report must cover the full calendar year to which it refers. If respondent's station was operated for part of the year under other ownership, the present and former licensees must file reports covering their respective periods of operation. Licensees are expected to file reports covering the period of the year for which they actually operated. It is the responsibility of the present licensee to make sure that the former licensee has filed a report for his period of operation.

4. When is report to be filed? On or before April 1.

5. Where is report to be filed? Federal Communications Commission, Policy Analysis Branch, Broadcast Bureau, Washington, D.C. 20554.

6. What special provision is made for licensees with revenue under $25,000? A respondent operating a commercial broadcast station and deriving total revenue of less than $25,000 for the year under report, or less than an average of $500 weekly if in operation for less than the year, is required to complete only Schedules 3, 4 and 5.

7. How shall network affiliation be reported in Item 6 of page 1 of the form? If the station is affiliated with two or more networks, all should be recorded. In the case of stations affiliated with more than one network, the network of primary affiliation should be recorded first. If the station changed from independent status to network affiliation, or the reverse, classify the station according to which status involved the most time during the year.

8. If the space provided for any schedule is insufficient or if it is necessary to insert additional statements, the insert pages shall be securely fastened in the report and shall be of durable paper conforming to this form in size and width of margin. Each insert shall bear the number and title of the schedule to which it pertains and the call letters.

9. If the licensee has two or more stations which share in certain income and/or expenses, he should allocate these joint items to the stations on a reasonable basis. For example, salaries should be allocated on the basis of the time worked for each station.

10. Use dollar figures only. Cents should not be shown.

INSTRUCTIONS FOR SCHEDULE 1 - BROADCAST REVENUES

Lines 4 and 5 of the schedule are designed to include the gross amounts of revenue earned from networks as compensation for the time of the respondent which was used by such networks for broadcasting network commercial programs. These lines should include revenue only from networks providing programs to a station. Revenue received from so-called "selling networks" (organizations which sell the station's time but do not provide it with any programs) should be reported on lines 8 or 9, according to the type of advertiser to whom time is sold. "Sale of station time to networks" means the amount received or receivable by the station from networks. Amounts paid by the networks for circuit costs, royalties, and similar items of expense which they furnish under contract are includible in the expense statement of the network. If, on the other hand, the stations pay for these items, either directly or through networks, as an offset against amounts receivable, such cash payments are includible in the expense statement of the station. These lines should not include revenue earned from the sale of network cooperative programs to non-network sponsors; the revenues retained by the stations after payments to the networks for such cooperative programs should be reported on lines 8 or 9.

Line 8 is designed to include the gross amount of revenue earned from advertising placed by or on behalf of advertisers generally recognized as national or regional in character. Usually this is the type of business commissionable to national representatives, but may be solicited directly by the respondent or through advertising agencies, brokers, or networks. Line 9 of the revenue statement is designed to include all gross revenue earned from time sales to local advertisers or sponsors. The distinction between line 8 and line 9 is based on the type of advertiser to whom the time is sold rather than how or by whom it is sold. In general, time purchased in behalf of retail or service establishments in the market should be considered local and reported on line 9. This is true even though the establishments are a part of a national or regional chain. The purchase of time by manufacturers or wholesalers are to be classified in lines 8 or 9 depending on whether the distribution area for the product extends to only the market under consideration (line 9) or to a larger region (line 8). Amounts reported on lines 8 and 9 are not to be reduced by cash discounts or amounts paid as commissions to advertising agencies, national representatives, and brokers, or to staff salesmen or employees.

Barter Transactions and Trade Outs: Include in lines 8 and 9 the value of trade outs or barter transactions. Report the total value of trade outs and barter transactions on line 20. Spots exchanged for program material should be estimated at a fair value consistent with purchases of other program material of similar quality and quantity. Spots exchanged for fixed assets (such as furniture, automobiles, studio equipment, etc.) should be estimated as the amount of cash which would have been required to purchase the asset.

Spots exchanged for merchandise (such as radio sets, television sets, sporting equipment, theatre tickets, novelty items, items to be used as prizes, gifts or give-aways), for advertisements in other media (such as newspapers, radio, television, transit ads, billboard, etc.), for services (such as hotels, travel, auto rentals, restaurants, etc.) are more difficult to value, but must be estimated for purposes of the financial report. Again, the amount of cash the station would have paid for the merchandise provides a reasonable basis for estimating the value.

NOTE: The value of traded merchandise or services should also be treated as any other cost items and expensed out or amortized (in Schedule 2) just as would cash purchases of similar merchandise or services.

Lines 13 and 14 include all amounts charged advertisers or sponsors (in connection with sales of time to them) for programs, materials, facilities or services; these lines exclude time charges reported in section A of Schedule 1.

Line 15 includes all broadcast revenue other than from time sales (line 11) and other than revenue reported in lines 13 and 14. Line 15 revenue derives from the supply of materials, facilities, or services which is not associated with the station's time sales. Examples are the rental of studio facilities for meetings, and fees received from others for the use of talent on the station's payroll.

INSTRUCTIONS FOR SCHEDULE 2 - BROADCAST EXPENSES

Line 3 includes such items as expenses for maintenance and repairs (other than payroll); parts or other expendable items which are not capitalized, such as tubes; power costs; and rental charges for transmitter lines.

Line 14 includes such items as circuit costs incurred in delivering programs to the local studio.

Line 18 includes expenses (other than payroll) incurred in connection with sales of time, advertising, promotion, and publicity.

General and Administrative expenses are those which cannot be classified in the technical, program, or selling categories.

Line 22 includes depreciation of tangible property and amortization of prepaid general and administrative expenses.

Line 22b is the amount paid for management services, including accounting, computer services and management fees, to either the home office or an affiliated branch or company under common control. This amount should also be included in reporting Line 4 of Schedule 3.

Line 23 includes such items as payments for legal and accounting services; insurance; and taxes (other than Federal income tax).

INSTRUCTIONS FOR SCHEDULE 3 - BROADCAST INCOME

This schedule is designed to show the profit or loss of the respondent from broadcast activities.

Line 4 should include amounts shown in line 22b, Schedule 2. Include also in line 4 amounts paid to or on behalf of (1) proprietors, partners or stockholders who own of record or beneficially 5% or more of the respondent, (2) any close relatives of such persons, (3) any organizations of which such persons or their close relatives are partners or the owners, directly or indirectly, of 5% of the equity securities, or (4) any trusts or other estates for the benefit of such persons or their close relatives. Close relative (as used here) means husband, wife, son, daughter, son-in-law, daughter-in-law, mother, father.

Payments of dividends or other payments from surplus are excluded from Line 4. If the respondent has more than one station, compensation paid to affiliated companies under common control, proprietors, partners, stockholders, or close relatives should be allocated on a reasonable basis among the stations.

INSTRUCTIONS FOR SCHEDULE 4 - EMPLOYMENT

Count all employees as "full-time" when they are employed for your normal basic work week. If the duties of certain full-time employees relate to two or more stations of the licensee, distribute these full-time employees among the stations in accordance with your best estimate of the proportion of their time devoted to the various stations.

INSTRUCTIONS FOR SCHEDULE 5 - TANGIBLE PROPERTY

Column (b) is the cost to the licensee of all tangible property in broadcast service. If the broadcast property is acquired as part of a going business (i.e., as a result of a station transfer), total cost should be the portion of the total price paid by the licensee which is properly assignable to tangible property.

Column (c) should reflect the balance in the accrued depreciation account resulting from accruals since acquisition of the property by the licensee, less net charges for property retired.

Line 4 should include such items as studio technical and production facilities, mobile equipment, office furniture, equipment and fixtures, automobiles and trucks.

BILLING CODE 6712-01-C

Appendix C: Alternate Schedule 4—Employment

Schedule 4. Employment

	Full-Time Employees	Individual Part-Time	Full-Time Equivalent TOTAL
Technical			
Local Programming			
Other Programming			
Selling			
G&A			
TOTAL			

Proposed Instructions - Schedule 4

Allocate staff time among the five categories. Estimates of time allocations are acceptable. Use the last payroll of the calendar year. Record only those personnel whose salary and/or wages were included in Schedule 2, Line 1 plus salespersons employed who are on commission only.

Record each employee as either full or part-time. Estimate in the "Total" column the number of equivalent full-time employees. For example, two part-time employees who work half time could be the equivalent of one full-time employee. In the "Total: Full-Time Equivalent" column, these two employees would be considered as one.

An employee who is involved in two or more functions should be allocated according to the time spent on each function. He (she) should be listed under Full-Time. Note that the total of Full-Time Employees must be a whole number.

BILLING CODE 6712-01-C

Appendix D: Alternative Schedule 5— Balance Sheet

Schedule 5 - Balance Sheet
December 31, 19__

(To be completed by the Licensees)

FCC Form 324

	Assets	Amount (omit cents)
	Current Assets	
1.	Cash	$
2.	Accounts Receivable	
3.	Inventories	
4.	Broadcasting Rights - current	
5.	Other Current Assets	
6.	Total Current Assets	
	Fixed Assets	
7.	Land and Buildings (depreciation to date $_____)	$
8.	Tower and Antenna Systems (depreciation to date $_____)	
9.	Transmitter Equipment (depreciation to date $_____)	
10.	All Other Fixed Assets (depreciation to date $_____)	
11.	Less: Total Accumulated Depreciation	
12.	Total Fixed Assets	$
	Other-Assets	
13.	Broadcasting Rights - Noncurrent	$
14.	Intangibles	
15.	Other	
16.	Less: Accumulated Amortization	
17.	Total Other Assets	$
18.	TOTAL ASSETS	$
	Liabilities and Owner's Equity	
	Current Liabilities	
19.	Loans Payable	$
20.	Accounts Payable and Accrued Expenses	
21.	Other Current Liabilities	
22.	Total Current Liabilities	$
	Non-Current Liabilities	
23.	Long-term Debt	$
24.	Deferred Items	
25.	Other Non-Current Liabilities	
26.	Total Non-Current Liabilities	$
	Owner's Equity	
27.	Retained Earnings	$
28.	Other Owner's Equity	
29.	Total Owner's Equity	$
30.	TOTAL LIABILITIES AND OWNER's EQUITY	$

Instructions - Schedule 5

Assets

Current Assets: Those assets which are expected to be converted into cash or consumed in business operations within a short period of time. (Normally one year or less).

Line 1	Cash	This classification includes cash on hand and on deposit in banks, including certificates of deposit.
Line 2	Accounts Receivable	Amounts due from advertisers and other trade accounts, and amounts due from officers, employees, and other non-trade parties should be included in this line item.
Line 3	Inventories	Include all inventories of tubes and supplies not yet used in programming and operations.
Line 4	Broadcasting Rights	The apportioned cost of feature films, other films, syndicated programs, and broadcasting rights to other programs expected to be used within the current year. The amount should be based upon estimated usage.
Line 5	Other Current Assets	All current assets not included in lines 1-3 should be contained in this line item, referring to short-term investments, prepaid expenses, and advances to parent or affiliates.
Line 6	Total Current Assets	The total of lines 1 through 5.

Fixed Assets: Capital assets used for operation which have a life expectancy of more than one year.

Line 7	Land and Buildings	The cost of land and buildings plus capitalized improvements should be entered on this line. The amount of accumulated depreciation applicable to these assets should be entered in the space immediately following the account title.

Line 8	Tower and Antenna System	The cost of the tower and antenna system should be entered on this line. The amount of accumulated depreciation applicable to this asset should be entered in the space immediately following the account title.
Line 9	Transmitter Equipment	The cost of technical equipment located at transmitter sites should be entered on this line. The amount of accumulated depreciation applicable to this asset should be entered in the space immediately following the account title.
Line 10	All Other Fixed Assets	The cost of studio and technical equipment, furniture, fixtures, mobile equipment, automobiles, construction in progress, and all other tangible fixed assets related to the broadcasting operation. The amount of accumulated depreciation applicable to these assets should be entered in the space immediately following the account title.
Line 11	Less: Total Accumulated Depreciation	The amount of depreciation expense charged to operation in all prior years should be included in this line item. This amount should equal the sum of the depreciation to date entered on lines 7 through 10.
Line 12	Total Fixed Assets	The sum of lines 7 through 10 less line 11.
Line 13	Broadcasting Rights - Non-current	The unamortized cost of feature films, other films, syndicated programs, and broadcast rights to other programs which are not expected to be broadcast within the current year.
Line 14	Intangibles	Include in this caption intangible assets such as goodwill, license costs, permit costs, and value of network affiliation.

Line 15	Other	All other non-current assets should be included in this caption, such as cash surrender value of life insurance, and advances to parent or affiliates.
Line 16	Accumulated Amortization	The amount of amortization expense charged to operations in all prior years should be included in this line item.
Line 17	Total Other Assets	The total of Lines 13, 14 and 15 less Line 16.
Line 18	Total Assets	The total of Lines 6, 12, and 17.

Current Liabilities: Those obligations to be liquidated by the use of existing current assets within one year.

Line 19	Loans Payable	This classification includes the current portion of long term debt and demand loans to be repaid within twelve months.
Line 20	Accounts Payable and Accrued Expenses	Include the amounts payable to suppliers and expenses accrued but not paid, such as interest and real estate and income taxes.
Line 21	Other Current Liabilities	All other current liabilities should be in this line item, including advances from parent or affiliates.
Line 22	Total Current Liabilities	The total of Lines 19 through 21.
Line 23	Long-Term Debt	Include in this caption total debt to be paid after twelve months.
Line 24	Deferred Items	Revenues that are deferred into a future operating period. This arises upon the receipt of an asset preceding the period in which the asset is considered to be earned, such as an investment credit or a tax liability.

Line 25	Other	All other non-current liabilities including advances from parent or affiliates
Line 26	Total Non-Current Liabilities	Total of Lines 23, 24 and 25.
Line 27	Retained Earnings	This classification should contain the accumulated earnings of prior periods, net of dividends declared This does not apply to proprietorships or partnerships
Line 28	Other Owner's Equity	Include in this caption the equity interests of partnerships and proprietorships (net of withdrawals) and other equity accounts such as paid in capital and donated capital.
Line 29	Total Owner's Equity	Total of Lines 27 and 28
Line 30	Total Liabilities and Owner's Equity	Total of Lines 22, 26, and 29

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Appendix E: Alternate Schedules 2 and 3—Summary of Expenses and Income Summary With Separation of Local and Nonlocal Programming Expense

Schedule 2. Broadcast Expenses

Functional Category

Line	Expense (a)	Tech (b)	Local Progr. (c)	Other Progr. (d)	Selling (e)	Gen'l & Admin. (f)	Total (g)
1	Salaries & Wages						
2	Payroll Taxes & Fringe Ben.						
3	Travel & Ent.						
4	Communication Exp.						
5	Facility Exp.						
6	Parts & Supplies						
7	Professional Fees						
8	Depreciation						
9	Amortization						
10	PROGRAM-LOCAL & OTHER:						
11	Rental & Amort of Film/Tapes						
12	Outside News Serv.						
13	Music License Fees						
14	Other Perf. & Prog. Rights						
15	SELLING:						
16	Commissions - Local						
17	Commissions - National						
18	Promo & Adv. Exp.						
19	GEN'L & ADMIN.						
20	Allocated Corp.Mgt.Exp.						
21	Allocated Corp.O.H.Exp.						
22	Other Expenses						
23	TOTAL						

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Alternate Instructions—Schedule.2

General Definitions

Functional Categories

1. *Column (b) Technical:* Technical Expenses.

This column includes, in the appropriate line item, all expenses related to the transmission of the station's signal, expenses incurred in maintaining the transmitter and the site, and expenses incurred in the studio and related areas which are considered to be of a technical nature. Salaries and fringe benefits paid to studio technicians, repair of broadcast equipment, etc., would be examples of such expenses.

2. *Column (c) Local Programming:* Local Program Expenses.

This column includes, in the appropriate line item, all expenses related to the production of programs originated or produced by the station. The expenses should include, but are not limited to, those involved in local news and public affairs.

3. *Column (d) Other Programming:* Other Program Expenses.

This column includes, in the appropriate line item, all program expenses which are not related to locally produced programs as defined in 2. above.

4. *Column (e) Selling:* Selling Expenses.

All expenses related to selling, advertising, or promotion of the station. Examples would be commissions to agencies or representatives and expenses related to salespersons' activities (phone, auto, etc.).

5. *Column (f) General and Administrative:* General and Administrative Expenses.

All expenses related to the management and administration of the station including overhead costs not allocated to other functions.

Note.—The allocation of expenses, where appropriate, should be based on a generally accepted cost accounting method. Time, space, and utilization are the major determinants of allocation.

Note.—For each line item, the total column is the sum of the preceding line entries (b+c+d+e+f=g).

Line 1.—Salaries and wages. For each functional category, enter salary and wages, including overtime, vacation, termination pay, sick leave, and bonuses. These salaries should be allocated among functional categories and employee time spent in each category. Estimates are acceptable.

Line 2.—Payroll taxes and fringe benefits. All city, state and Federal related payroll taxes as well as fringe benefits such as insurance, pension, etc. should be included here. The allocation among functional categories should be performed in the same manner as Line 1.

Line 3.—Travel and entertainment. This should include travel, entertainment, and automobile related costs. Lease or rental of automobiles is to be included. This is to be allocated by functional category on the basis of use, either actual or estimated.

Line 4.—Communication expenses. This includes telephone and telegraph, postage, membership dues and subscriptions, and courier services. Again, this is to be allocated by usage, either actual or estimated.

Line 5.—Facility expenses. Includes rent or lease expenses, utilities (heat, light, power), property related taxes (no other taxes), and maintenance and repair.

Line 6.—Parts and supplies. Expenses to be included vary by functional category. The bulk will be under Technical, such as tape, equipment parts, and supplies (excluding tubes), or under G&E, such as general office supplies.

Line 7.—Professional fees. Fees paid to persons not on the station payroll for the provision or professional services.

Technical (Column b)—Technical consulting and engineering fees.

Local Programming (Column c)—talent fees; fees paid to other than staff for work such as announcers, consultants, actors, technicians, directors, etc.

Other Programming (Column d)—Same items as Column c, but not related to locally produced programming.

Selling (Column e)—consultant expenses, etc.

G&A (Column f)—legal, auditing, consulting.

Line 8.—Depreciation. Varies by functional categories.

Technical: Include depreciation of studio, transmitter, and other technical equipment. For example, this would include cameras, mobile production facilities, tape machines, transmitters, towers, etc.

Local programming: Include depreciation of non-technical (non-electronic) plant and equipment utilized for local programming.

Non-local programming: Include depreciation of non-technical (non-electronic) plant and equipment utilized for programming other than local produced.

Selling: Depreciation of assets utilized by sales and promotion department.

G&A: Depreciation of all assets which cannot be allocated to any of the above four functional categories.

Line 9.—Amortization. Varies by functional categories.

Technical: Amortization of leasehold and land improvements considered to be utilized for technical (transmitter, tower, etc.) purposes.

Local programming: Amortization of those assets or portion thereof utilized in local programming *EXCEPT* the value of programs held as assets. Includes studio.

Other programming: Amortization of those assets or portion thereof utilized in programming other than locally produced *EXCEPT* the value of programs held as assets. Includes studio.

Selling: Amortization of any assets utilized in selling.

G&A: All remaining amortization costs *not* included in any of the four above *nor* to be included in Line 13, Rental and Amortization of Film and Tape *or* Line 18, Other Performance or Program Rights. An example is amortization of intangibles, such as good will.

Program (Local and Other)

Line 11.—Rental and amortization of films and tape. Include the rental cost of and the value of feature film and syndicated program expense amortized during the report year. Do not include other film expenses such as raw stock, processing costs, shipping, audio tape, etc.

Line 12.—Outside news service. The cost of outside news service such as A.P. and U.P.I. Also include cost of news stringers.

Line 13.—Music license fees. Amounts paid to ASCAP, SESAC, BMI, and others.

Line 14.—Other performance and program rights. Cost and/or amortization of rights to broadcast programs not included in lines 11, 12 and 13. For example, this line would include the amortization of rights to sports and special events.

Selling Expenses

Line 16.—Commissions—local. All commissions to agencies, reps, and brokers who are considered local. Include commissions paid to licensee's sales force.

Line 17.—Commissions—national. All commissions to agencies, reps, and brokers who are considered national and/or regional.

Line 18.—Promotion and advertising expenses. Include all trade and audience promotion and advertising expenses.

General and Administrative

Line 20.—Allocated corporate management expenses. Management expenses allocated by the home office or affiliate. Included would be the allocated cost of time spent by legal and accounting professionals for services

rendered to the licensee, if not billed directly. Do not include interest expense.

Line 21.—Allocated corporate overhead expenses. Common overhead expenses allocated by home office to licensee. Include those expenses *not* in Line 22, Allocated Corporate Management Expense. For example, charges from the home office for use of a central computer or billing service and allocated costs of maintaining the home office. Do not include allocated interest expense, which will be included in Schedule 3, Line 10.

Line 22.—Other expense. The accounts which go into each "other expense" line vary by functional (Technical, Local Program, Other Program, Selling, and G&A) category.

Technical: Include any expense appropriate to the technical function which has not yet been recorded.

Local programming: Include film expenses such as raw stock, processing and shipping, studio sets and props, program materials and facilities, records and transcriptions, audio tape, and other expenses related to local programming not elsewhere included in Schedule 2.

Other programming: Include film expenses, line charges, co-op fees, outside origination costs, and other program expenses not elsewhere included in Schedule 2.

Selling: Include cost of rating services, audience research, and any other selling expense not elsewhere included in Schedule 2.

G&A: Include such costs as non-allocable insurance, charitable contributions, FCC license fees, corporate fees, miscellaneous state and local taxes (other than income), bad debt accounts, and other operating expenses which are neither allocable not included in other line items. Be sure *not to include* non-operating expenses as mentioned in Schedule 3.

BILLING CODE 6712-01-M

Alternate Schedule 3. Income

Line			
1	BROADCAST REVENUE		$_____
	OPERATING EXPENSE:		
2	Technical Expense	$_____	
3	Local Program Expense	_____	
4	Other Program Expense	_____	
5	Selling Expense	_____	
6	G&A	_____	
7	TOTAL OPERATING EXPENSE		$_____
8	OPERATING INCOME		$_____
	Other Income and Expense		
9	Non-Operating Revenue	$_____	
10	Interest Expense	(_____)	
11	All Other Non-Operating Expense	(_____)	
12	NET NON-OPERATING INCOME		$_____
13	INCOME BEFORE TAXES		_____
14	Federal and State Income Tax		(_____)
15	NET INCOME		$_____
16	PAYMENTS TO PRINCIPALS Total Salaries, Interest, and Other Payments to Principals:		$_____

BILLING CODE 6712-01-C

Alternate Instructions—Schedule 3

Line 1.—Broadcast revenue. Enter the total from Schedule 1, Line 14.

Line 2.—Technical expense. Schedule 2, Line 25(b).

Line 3.—Local program expense. Schedule 2, Line 25(c).

Line 4.—Other program expense. Schedule 2, Line 25(d).

Line 5.—Selling expense. Schedule 2, Line 25(e).

Line 6.—General and administrative expense. Schedule 2, Line 25(f).

Line 7.—Total operating expense. Schedule 2, Line 25(g). This should also equal the total of Lines 2 through 6 above.

Line 8.—Operating income. Line 1 less Line 7.

Line 9.—Non-operating revenue. Include all revenues accruing to the station which were not part of its broadcast operation. Examples are interest received, rent, and gain on investments or sale of assets.

Line 10.—Interest expense. All interest, either accrued by the station or allocated from the home office.

Line 11.—All other non-operating expense. Include all other expenses accruing to the station which were not part of its broadcast operation. For example, loss on investments or sale of assets.

Line 12.—Net non-operating income. Line 9 less Lines 10 and 11.

Line 13.—Income before taxes. Line 8 plus Line 12.

Line 14.—Federal and State income tax. The amount of income tax expense recorded for report year.

Line 15.—Net income. Line 13 less Line 14.

Line 16.—Payments to principals. Total salaries, interest and payments (excluding dividends and profit distributions) to principals or on behalf of principals which total more than $250 annually and are reported as part of expenses in Schedule 2. An example would be auto lease paid to principal of $50/month or $600/year. Include in an attachment a summary of the specific payments from which this figure is derived. State the number of principals receiving salary.

Principals are defined as owners/stockholders or the owner's immediate family—parents, wife, husband, children, in-laws, and siblings.

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BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 533

[Docket No. FE 78-01; Notice 3]

Light Truck Average Fuel Economy Standards; Limited Extension of Deadline for Public Comment

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Limited extension of deadline for submission of public comments.

SUMMARY: This notice extends the deadline for submitting written comments on NHTSA's proposed light truck average fuel economy standards for model years 1983–85. This extension is limited to comments on two recent submissions from the Regulatory Analysis Review Group (RARG) and the Department of Energy (DOE). This action is being taken to provide the public an opportunity to comment on alternative proposals for light truck fuel economy standards developed by other Federal agencies involved in this rulemaking proceeding.

DATE: Comments on these two submissions must be received by NHTSA no later than June 26, 1980

ADDRESSES: Comments must be submitted (preferably in 10 copies) to the Docket Section, Room 5108, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, D.C. 20590. Submissions containing information for which confidential treatment is requested should be submitted (preferably in three copies) to the Chief Counsel, National Highway Traffic Safety Administration, Room 5219, 400 Seventh Street, SW, Washington, D.C. 20590, and seven additional copies from which the purportedly confidential information has been deleted should be sent to the Docket Section.

FOR FURTHER INFORMATION CONTACT: Mr. Philip W. Davis, Office of Automotive Fuel Economy Standards, Room 4102, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, D.C. 20590 (202–472–6902).

SUPPLEMENTARY INFORMATION: On December 31, 1979, in 44 FR 77199, NHTSA proposed the issuance of average fuel economy standards for light trucks manufactured in model years 1982–85. A 30-day period was established for the submission of comments on the 1982 standard, due to a statutory deadline for issuance of that standard and the complex marketing and other issues involved in setting standards for the later model years. A 90-day comment period (ending March 31, 1980) was established for the 1983–85 standards. On the latter date, in 45 FR 20871, the 1982 standards were published.

Among the comments received on the 1983–85 standards were two from Federal agencies involved in fuel economy and regulatory matters, RARG and DOE. Because of the significance of these comments and the important role which each of these agencies plays in this rulemaking proceeding, NHTSA has decided to publish this special request for comments on the submissions of those two agencies.

RARG was established by Presidential directive to assist the various Federal agencies in assuring that their regulations meet statutory goals with minimum cost and burden to the regulated companies. See Memorandum From the President, October 31, 1978, Volume 14, Weekly Compilation of Presidential Doucments at 1905–6. It is chaired by the Council of Economic Advisers, and has as members the principal economic and regulatory agencies of the Executive Branch. Staff support is provided by the Council on Wage and Price Stability. RARG selects for review particular regulations which have a large economic impact or are otherwise controversial, and submits comments on the regulation to the agency which proposed it, as part of the normal public comment process. The 1983–85 light truck fuel economy standards were selected by RARG as one of the regulations to be reviewed.

RARG submitted three general comments on the proposed light truck standards. First, RARG argued that NHTSA should consider using a cost-benefit procedure in assessing various levels of standards. This analysis would be based upon the most accurate data available and would attempt to take into account certain nonquantifiable costs and benefits of higher fuel economy, such as reductions in truck utility and national security benefits. The interrelationship between passenger car and light truck capital requirements would also be considered. Under the RARG proposal, this analysis would not be determinative of the level at which standards would be set, but would be used as an aid in determining the level of standards which are in the national interest.

RARG's submission also indicated that it supports NHTSA's legislative proposals for providing increased flexibility for the manufacturers in

complying with fuel economy standards. These proposals include an extension from one year to three years of the period for carrying forward or back monetary credits earned for exceeding fuel economy standards (to be applied to penalties for noncompliance in earlier or later years). Also included in these proposals was a recommendation that noncompliance with fuel economy standards not be deemed "unlawful conduct" when offsetting credits can be applied from earlier or later years in which standards are exceeded. RARG argues for a third statutory amendment which would also provide the manufacturers additional flexibility in complying with standards. This amendment would permit credits to be transferred between cars and trucks and between classes of light trucks. Currently, the law permits credits earned for exceeding passenger automobile standards to be applied only to penalties assessed against passenger automobiles. Similarly, credits earned for one class of light trucks (e.g., 2-wheel drive trucks) can only be used to offset penalties assessed against that same class.

RARG's third proposal involves the establishment of separate "composite" fuel economy standards for each manufacturer. Establishing such a standard would involve setting fuel economy targets for different classes of light trucks and combining those numbers into a sales-weighted average fuel economy level which would be the composite standard. For example, the composite standard could be a sales-weighted average of the maximum feasible fuel economy levels currently determined on an industrywide basis for 2-wheel drive light trucks and for 4-wheel drive light trucks. The sales weighting for a particular manufacturer would be based upon the relative proportion of these two classes of light trucks in that manufacturer's fleet in some base year. Thus, the level of the composite standards would vary from manufacturer to manufacturer.

An example of how a 2-wheel drive/4-wheel drive composite standard would work if it applied in 1982 is as follows.

The maximum feasible average fuel economy levels for 1982 2- and 4-wheel drive light trucks were determined by the agency to be 18 and 16 mpg, respectively. If company A sold 75 percent 2-wheel drive light trucks and 25 percent 4-wheel drive light trucks in the base year, its 1982 composite standard would be the sales weighted, harmonic average of 18 and 16 mpg, or 17.5 mpg. If company B sold 60 percent 2-wheel drive light trucks and 40 percent 4-wheel drive light trucks in the base year, its 1982 composite standard would be 17.1 mpg. Thus, company B would be subject to a less stringent fuel economy standard for 1982 regardless of the mix of trucks actually sold in that year.

The composite standard is intended to provide manufacturers additional means of complying with fuel economy standards, such as by increasing the sales of the more fuel efficient class (2-wheel drive in the above example) of light trucks and decreasing the sales of the less efficient (4-wheel drive). Also, manufacturers would be given greater flexibility to make fuel economy improvements which only affect one class of light trucks. For example, were a manufacturer to make a major investment to redesign its vans, that investment would be of no assistance in meeting NHTSA's fuel economy standard for 4-wheel drive light trucks, since all vans are currently 2-wheel drive. Thus, manufacturers might opt for making lesser fuel economy improvements to all its light trucks. This approach might not provide any more fuel savings than would making major improvement to a portion of the fleet and might even cost more. Ford Motor Company has advocated a variation of this proposal, in which the composite standard would apply at the option of the manufacturer.

Because of the significance of the RARG proposals, the agency is inviting comment on those proposals. In particular, the agency invites comment on the following issues with respect to the composite standard proposal:

1. Is the establishment of composite standards, in which different numerical requirements would apply to different companies depending on a base year fleet mix, authorized under the Motor Vehicle Information and Cost Savings Act?

2. Is the composite standard approach desirable from the point of view of national policy? What would be the competitive and other effects of such a standard?

3. If composite standards were adopted, what base year fleet mix should be used?

Although the RARG proposal on transferring monetary credits between passenger automobiles and light trucks and between classes of light trucks would require legislative action and is therefore beyond the scope of this proceeding, the agency also invites comment on the desirability of that proposal.

Sections 502(h) and (i) of the Motor Vehicle Information and Cost Savings Act provide specifically for the Secretary of Energy to comment on and participate in fuel economy standard-setting. With respect to this proceeding, DOE has provided a comprehensive re-analysis of the 1985 2-wheel drive fuel economy standard and suggested that the 1985 standards be set at levels of 24 mph for 2-wheel drive light trucks and 20 mpg for 4-wheel drive light trucks. These levels are above the upper end of the ranges of fuel economy standards which NHTSA proposed for that year.

The major differences between the DOE and NHTSA analyses for 1985 are as follows:

1. DOE used 1980 fuel economy test data and 1979 sales information (modified to reflect the elimination of certain engines for 1980) in developing a baseline for projecting future model year fuel economy. NHTSA's baseline, on the other hand, was the 1981 standards (with certain minor modifications), which in turn were based on 1979 sales and fuel economy data.

2. Using 1980 fuel economy data, DOE developed new exponents for the regression equation NHTSA used for determining the effect on fuel economy of changes in vehicle weight, engine displacement, and rear axle ratio. The DOE exponents yield larger improvements in fuel economy from a given reduction in weight, engine displacement or axle ratio than those used by NHTSA. DOE also developed a more complex model for projecting the fuel economy improvement resulting from changes in the previously mentioned vehicle attributes. That model, which was used by DOE in its analysis, also yields higher results than the NHTSA equation.

3. DOE made slightly higher estimates of the fuel economy benefits resulting from various types of technology.

4. DOE included the benefits of diesel engines in its analysis.

5. DOE projects that future compact truck models could have higher fuel economy than did NHTSA. For example, DOE argues that domestic small trucks need be no larger than current imports and could use exclusively 4-cylinder engines, as the imports do. NHTSA in the rulemaking support paper for the proposed 1982–85 standards assumed that future domestic compact trucks would be no larger than intermediate in size between current imported trucks and the large domestic models, and would use a mix of 4 and 6 cylinder engines.

The agency invites comments on the DOE analysis and in particular the major assumptions underlying that analysis.

A 30-day comment period is being provided due to the relatively limited scope of the issues raised, and the need

for the agency to proceed rapidly to establish final fuel economy standards for 1983–85. Copies of the RARG and DOE submissions are available from NHTSA's Docket Section, Room 5108 of the Nassif Building in Washington, D.C.

All comments must be limited not to exceed 15 pages in length. Necessary attachments may be appended to these submissions without regard to the 15 page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

It is requested but not required that 10 copies of all comments be submitted to the address specified at the beginning of this notice. If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. Any claim of confidentiality must be supported by a statement demonstrating that the information falls within 5 U.S.C. section 552(b)(4), and that disclosure of the information would result in significant competitive damage; specifying the period during which the information must be whitheld to avoid that damage; and showing that earlier disclosure would result in that damage. In addition, the commenter or, in the case of a corporation, a responsible corporate official authorized to speak for the corporation must certify in writing that each item for which confidential treatment is requested is in fact confidential within the meaning of section 552(b)(4) and that a diligent search has been conducted by the commenter or its employees to assure that none of the specified items has previously been disclosed or otherwise become available to the public.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking. The NHTSA will continue to file relevant material as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose, in the envelope with their comments, a self-addressed stamped postcard. Upon receiving the comments, the docket supervisor will return the postcard by mail.

(Sec. 9, Pub. L 89–670, 80 Stat. 931 (49 U.S.C. 1657); sec. 301, Pub. L 94–163, 89 Stat. 901 (15 U.S.C. 2002); delegations of authority at 49 CFR 1.50 and 49 CFR 501.8)

Issued on May 8, 1980.

Michael M. Finkelstein,

Associate Administrator for Rulemaking.

[FR DOC. 80-15828 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-59-M

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49 CFR Part 571

[Docket No. 80–9; Notice 1]

Lamps, Reflective Devices and Associated Equipment; Federal Motor Vehicle Safety Standards

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice announces that NHTSA is considering the proposal of an amendment to Safety Standard No. 108 to improve the noticeability of large commercial vehicles. The primary purpose of the proposal would be to improve the probability of motorists seeing larger vehicles on the road in order to reduce the likelihood of running into them. The performance criteria that might be proposed could revise existing location and photometric (e.g., luminous brilliance, luminous flux, light distribution, color, etc.) requirements for truck and trailer lighting, signalling and marking systems.

DATES: Comment closing date: August 25, 1980.

ADDRESSES: Comments should refer to the docket number and notice number and be submitted to: Docket Section, Room 5108 Nassif Building, 400 Seventh Street, SW., Washington, D.C. 20590. (Docket hours 8 a.m. to 4 p.m.)

FOR FURTHER INFORMATION CONTACT: Kevin Cavey, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, Washington, D.C. 9202–426–2715).

SUPPLEMENTARY INFORMATION: NHTSA is considering the issuance of a proposal to amend Motor Vehicle Safety Standard No. 108 to require improved conspicuity of large commercial vehicles. Conspicuity is the property of an object that determines its likelihood of being seen. The purpose of the amendment would be to prevent accidents in which these vehicles are struck by other vehicles in the rear or side. This improved conspicuity could be accomplished by better lighting and signalling systems and/or increased use of reflectorized and fluroescent materials.

The potential safety value of improved conspicuity is indicated by the English experience with this measure. Since November 1, 1971, vehicles over three tons unladen weight in England have been required to display distinctive rear markings. The markings incorporate yellow reflective material (to improve nighttime conspicuity) and red fluorescent material (to improve daytime conspicuity). The markings consist of two patterns: (1) Diagonal (chevron) stripes for vehicles of less than 13 meters (42.5 feet) overall length; and, for longer vehicles (2) a sign with the reflective and fluorescent coating as a backgroung. The results indicate a reduction in the number of accidents across all lighting conditions after the introduction of the markings, and a significant reduction for parked vehicles at night on unlit rural roads. However, England does not have any requirements like those in Standard No. 108 for large commercial vehicles to be equipped with identification and clearance lamps. Hence, reflectorized materials are considered more effective and essential to truck and trailer conspicuity in England than in this country.

It is obvious that avoidance of a collision is far more beneficial than mitigating the injuries associated with it. However, the agency recognizes the fact that even with better detectability, some collisions will occur. It is expected that improved conspicuity will assist in preventing collisions during times of reduced light, but not necessarily during daylight.

The agency is currently developing rulemaking jointly with the Bureau of Motor Carrier Safety (BMCS) of the Federal Highway Administration, specifically to upgrade the existing BMCS regulation 49 CFR 393.86—*Rear End Protection.* This regulation currently covers vehicles in interstate commerce only. Proposed regulations will consist of a Federal motor vehicle safety standard and an amendment to the existing BMCS regulation. The NHTSA proposed standard would specify performance requirements for rear underride protection devices and would apply to all new trucks and trailers

which weigh more than 10,000 pounds (GVWR). The amended BMCS regulation would contain the same performance requirements as the NHTSA standard and would apply to all trucks in use in interstate commerce.

The proposed rear end protection rule is intended to provide improved safety for occupants of passenger cars which do not avoid a rear end collision with a heavy vehicle. The effort will focus on geometric and strength properties for rear underride devices to achieve improved safety. The combination of improved conspicuity and rear end protection should significantly reduce the risk of personal injury and property damage.

The Safety Problem

Accidents involving vehicles running into trucks or trailers are severe events. An analysis of 1978 accident data from NHTSA's Fatal Accident Reporting System (FARS), indicates that there were 936 accidents causing 1,018 fatalities in which vehicles ran into the side or rear of trucks or trailers. Of the 936 striking vehicles, 640 were passenger cars accounting for 698 fatalities. Similar accidents involving injuries are estimated to number about 20,000.

A large number of the fatalities potentially preventable by improved conspicuity appear to be those which occurred after dark, or during periods of reduced light such as dusk and dawn. Of the 640 accidents in which cars struck heavy trucks or trailers, 436 (68 percent) occurred in the dark or in reduced light conditions. Of the 936 fatal accidents, 500 (53.4 percent) occurred in the dark or under reduced light conditions, and at least 96 of the 494 (10 percent of 936) were collisions with stopped trucks.

In October 1977, Minahan and O'Day (HSRI) published a report entitled "Car-Truck Fatal Accidents in Michigan and Texas" which that 57 percent of the collisions in which the passenger compartment of a smaller vehicle contacts the rear or side of a larger vehicle involved running into the rear of a truck, and that 70 percent of the trucks in these collisions were tractor-trailer combinations. Further, according to these data a fatal collision is more likely if the smaller vehicle strikes the rear of the truck rather than the side. Also, Minahan and O'Day, in an analysis of the 1977 FARS data, found that a disproportionate number of the vehicles struck in the rear at night are large trucks leading the researchers to conclude that improved conspicuity might be an appropriate countermeasure.

The agency has reason to believe that a causal factor in these accidents is the inability of the driver of the striking vehicle to recognize the imminence of a hazard. For example, from 1967 through 1975, the Office of Research of the Federal Highway Administration (FHWA) conducted an in depth special study of commercial vehicle accidents involving vehicles parked or stopped on highway shoulders (DOT-FH-11-8835, 1975). This study covered 400,000 accidents which accounted for 20,000 fatalities, 250,000 injuries, and 1 billion dollars in property damage. The findings of the study indicate that about 20 percent of the accidents might have been prevented or reduced in severity by improving vehicle conspicuity, specifically about 14 percent in which the rear of the truck was impacted and an additional 6 percent in which side impacts were involved.

The Minahan and O'Day study of fatal car-into-truck underride collisions in Texas and Michigan concluded that two-thirds of all underride accidents occur at night. This fact along with the finding that impact speeds were high, emphasize that underride accidents are surprise events in which the drivers of the striking vehicles apparently do not see the other vehicles in time to stop. This suggests that increasing the conspicuity of trucks, and especially truck-trailers, at night may prevent some of these accidents from occurring.

Although the agency has some accident data, more are needed to better understand the factors involved, especially the causal factors. Questions for which the agency seeks specific information from commenters include:

1. How many non-fatal accidents occur annually involving smaller vehicles running into the rear or sides of larger commercial vehicles?

2. Are there other studies suggesting that the driver of the striking vehicle could not see the struck vehicle?

3. Are there fleets that have taken steps to improve the conspicuity of their trucks and trailers for which rear and side impact accident data may exist or could be collected?

4. Are accident data available or collectable that would make possible a comparison of the rear and side impact accident involvement rate of trailers with low-mounted clearance and identification lamps (e.g., flat bed trailers) and van trailers with high mounted clearance and identification lamps?

5. Are there other studies or data available or collectable that permit the accident experience of vehicles with differing conspicuity to be compared?

The Problem of Conspicuity

The data discussed above implies that drivers run into other vehicles because they don't see or notice them, and that improved conspicuity will result in a reduction in accidents. The primary physical parameters affecting the visibility of objects are size, luminance, and contrast.

Presently, large vehicles are required by Standard No. 108, to have headlamps, identification lamps, clearance lamps, stop lamps, side marker lamps, turn signals, and red and amber reflectors. Even though heavy-duty vehicles are large and contrast with their environment and have all the above mentioned lamps and reflectors, rear and side collisions still occur. It is a known fact from various research that the amber and red lights can be seen from distances greater than 2500 feet, and that the reflectors can be detected at distances of 2000 feet. (The Detection and Recognition of Disabled Vehicles, Driving Research Laboratory DRL-RR-67-1; Night Demonstration on Conspicuity of Trucks and Trailers, 3M Company, St. Paul, Minnesota, November 9, 10, 1978; and Reid, J.A., "Recognition Distances of Vehicles Rear Markings at Night," Transport and Road Research Laboratory, Crawthorne, England, Supplementary Report 321, 1977). This illumination and reflectorization should be adequate for the motorist to see and perform evasive action when necessary. This leads the agency to conclude that it does not have sufficient information to understand why this illumination and reflectorization on large vehicles is not sufficiently conspicuous (attention-getting) to prevent rear and side accidents on what changes should be made to improve their conspicuity. Questions about vehicle conspicuity for which the agency seeks specific information from commenters include:

1. Why do rear and side impact accidents seem to involve a failure to see the struck vehicle when that vehicle has an apparently sufficient amount of lamps and reflectors to be capable of being seen under all conditions of daylight, nighttime, and inclement weather?

2. Are there any data indicating that deterioration of light output or reflectorization due to dirt or poor vehicles maintenance contributes to these accidents?

3. Should steady burning or flashing special signals or lamps be added to vehicles to indicate a decelerating or slow-moving or parked heavy vehicle?

4. Current research indicates that rear-end collisions involving passenger

cars can be significantly reduced by installing an additional, high mounted, centrally located brake lamp. Would additional lamps or reflectorized materials on commercial vehicles interfere with this type of signal, the present brake lamp, or turn signal, or in some other manner confuse the driving public?

5. Does the present configuration of truck lighting (i.e. number, type and location of lamps and reflectors) tend to confuse drivers and if so, in what manner?

The Problem of Reflectorization

Better or additional methods of gaining the attention of motorists may be needed. Available human factors data suggest that safety could be improved by making changes to the present lighting scheme. For example, lamps could be bigger and brighter, and have more contrast than existing systems. Or the use of fluorescent materials could improve daytime conspicuity, and additional reflective materials might enhance it at night. Changes in the lighting and reflectorization patterns may also improve conspicuity.

The reflectorization quality of material depends upon the various factors such as the squareness in the cut of the prism sides, and the smoothness of the surfaces. These characteristics can be controlled when the reflectors are manufactured.

The color of the reflective material should be given consideration when discussing increased conspicuity during the dusk and nightime hours. Red, for instance, will reflect light only one-fourth (¼) the amount that white will.

Although some fleets presently use reflectorized tapes for ease of identification, the NHTSA wishes additional information on the desirability of reflectorization such as using reflectorized barrier designs on the sides and rear of new trucks and trailers.

Questions about reflectorization for which the agency seeks specific information from commenters include:

1. What is the experience of manufacturers and users with reflectorized tape materials with respect to installation cost, durability, maintenance costs, lifetime, effectiveness when dirty, and ease of application, maintenance and repair?

2. Would a conspicuity-enhancing requirement that could be met by use of reflectorized material as an advertisement, applied as the manufacturer wishes, be more acceptable to the industry than one which requires that such material be installed in a certain manner specified by the standard?

3. Would adding large amounts of reflectorization lead to more instances of vehicles running into trucks parked on the side of the roadway by diverting the driver's attention from the road?

4. Should the color of reflectorized material on the rear of trucks be changed from red to some other color that reflects light in a more efficient manner?

5. Should specifications be adopted for squareness in the cut of prism sides and smoothness of surfaces?

6. Would a change in the present lighting and reflectorization patterns enhance safety?

The Problem of Maintenance

The side and rear lamps required by Standard No. 108 are sometimes positioned so that they are subject to splash and spray during inclement weather, reducing light output. In addition, the voltage drop (mainly due to the distance from the electric power source and to the size of the conductor) can cause a reduction in brightness. Because of these factors the conspicuity of the truck may be seriously impaired. Questions about maintenance for which the agency seeks specific information from commenters include:

1. How can operators insure that the exterior lamps and reflective materials are adequately maintained?

2. Would changing the positions of certain lamps, such as lowering the clearance and identification lamps, encourage improved maintenance?

3. What is the magnitude of voltage drop?

The Department's Bureau of Motor Carrier Safety of the Federal Highway Administration is monitoring this rulemaking action and related research activity.

This notice has been evaluated under the criteria of E.O. 12044, "Improving Government Regulation," and under departmental guidelines implementing that order. Due to the agency's lack of certain data and to the uncertainty about the type and level of the requirements and test conditions that might be proposed, the agency cannot at this point reach specific conclusions concerning the effects of the potential proposal. Therefore, the agency cannot yet detemine whether the potential regulation will be significant. Nevertheless, the agency is confident that this approach would bring forth substantial safety benefits. Further, the costs involved are relatively modest and the technology required is already available. A brief and preliminary regulatory evaluation has been prepared and is available from the NHTSA docket section by writing to the address given at the beginning of this notice. After the agency reviews the comments on this notice and conducts further analyses and before it issues any notice of proposed rulemaking, the agency will again examine the effects of the regulation. The agency will determine whether the regulation is significant and prepare the appropriate document discussing those effects. That document will be made available for public comment.

The engineer and lawyer primarily responsible for the development of this notice are Kevin Cavey and Taylor Vinson respectively.

Comments

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must be limited not to exceed 15 pages in length. Necessary attachments may be appended to these submissions without regard to the 15 page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. Any claim of confidentiality must be supported by a statement demonstrating that the information falls within 5 U.S.C. section 552(b)(4), and that disclosure of the information is likely to result in substantial competitive damage; specifying the period during which the information must be withheld to avoid that damage; and showing that earlier disclosure would result in that damage. In addition, the commenter or, in the case of a corporation, a responsible corporate official authorized to speak for the corporation must certify in writing that each item for which confidential treatment is requested is in fact confidential within the meaning of section 552(b)(4) and that a diligent search has been conducted by the commenter or its employees to assure that none of the specified items has previously been disclosed or otherwise become available to the public.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for

examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking. The NHTSA will continue to file relevant material as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose, in the envelope with their comments, a self addressed stamped postcard. Upon receiving the comments, the docket supervisor will return the postcard by mail.

(Secs. 103, 119, Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392, 1407); delegations of authority at 49 CFR 1.50 and 501.8)

Issued on May 8, 1980.

Michael M. Finkelstein,

Associate Administrator for Rulemaking.

[FR Doc. 80-15823 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-59-M

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49 CFR Part 575

[Docket No. 25; Notice 40]

Consumer Information Regulations, Uniform Tire Quality Grading

AGENCY: National Highway Traffic Safety Administration.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: This notice modifies a previous proposal to amend the traction and temperature resistance test procedures of the Uniform Tire Quality Grading (UTQG) Standards to make provision for the testing of tires with inflation pressures measured in kilopascals. This notice also extends the proposal to include testing of "metric" tires for treadwear. The notice is intended to facilitate the testing of "metric" tires for Uniform Tire Quality Grading by providing test procedures directly applicable to such tires. The notice also proposes modification of previously proposed changes in traction test procedures to further encourage efficient use of test facilities.

DATES: Comments must be received on or before June 26, 1980. Proposed effective date: Date of publication of the final rule in the Federal Register.

ADDRESSES: Comments should refer to the docket number and be submitted to Room 5108, Nassif Building, 400 Seventh Street SW., Washington, D.C. 20590.

FOR FURTHER INFORMATION CONTACT: Dr. F. Cecil Brenner, Office of Automotive Ratings, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, D.C. 20590, 202-426-1740.

SUPPLEMENTARY INFORMATION: On October 1, 1979, the National Highway Traffic Safety Administration (NHTSA) published a notice (44 FR 56389) proposing to modify the traction and temperature resistance test procedures of the UTQG Standards (49 CFR 575.104) to provide for testing of "metric" tires, (i.e., tires with inflation pressures measured in kilopascals) and to revise the traction test procedures to permit more efficient use of test facilities. With regard to traction testing, NHTSA proposed that candidate tire test runs be permitted either before or after the standard tire test sequence to which the candidate tire results are compared for adjustment for environmental and other factors. The present regulation requires the completion of the standard tire test sequence prior to the commencement of candidate tire test runs. The proposed amendment would have required all candidate and standard tire tests, the results of which are compared, to be completed within a single, two-hour period.

In its October 1 notice, the agency also proposed that paragraphs (f)(2)(i)(B) and (D) and (f)(2)(viii) of the traction test procedures (49 CFR 575.104(f)(2)) be amended to provide for inflation and loading of metric tires at 180 kilopascals, rather than 24 pounds per square inch, as is now required for all tires. It was proposed that loading of metric tires for the temperature resistance test be determined at the inflation pressure which is 40 kPa less than the tires' maximum permissible inflation pressure. The standard now specifies 8 psi less than maximum permissible inflation pressure.

In commenting on NHTSA's proposal, the Goodyear Tire and Rubber Company and the BFGoodrich Company suggested that additional provisions of the UTQG test procedures also be amended to accommodate testing of metric tires. Specifically, these commenters suggested that paragraphs (e)(2)(ii) of the treadwear test procedures (49 CFR 575.104(e)(2)) and (g)(1), (3), and (8) of the temperature resistance test procedures (49 CFR 575.104(g)) be amended. Since these paragraphs specify test conditions in terms of pounds per square inch, rather than kilopascals, NHTSA believes that these sections should also be amended to facilitate metric tire testing.

Goodyear and Goodrich pointed out that the proposed specifications of tire test inflation pressures at a particular number of units (e.g., 60 kPa below maximum permissible inflation pressure) does not take into account the special situation of tires with a maximum inflation pressure of 300 kPa. Under Standard No. 109, New Pneumatic Tires (49 CFR 571.109), these tires are tested at an inflation pressure well below maximum permissible inflation pressure. Both Goodyear and Goodrich suggested that use of a table, such as Table III of Standard No. 109, stating test inflation pressures for various maximum permissible inflation pressures, would be the clearest way of identifying inflation pressures for UTQG testing. While Goodyear specifically discussed use of a table for treadwear and temperature resistance testing only, Goodrich suggested that a table would be appropriate for traction testing as well. Goodrich also suggested that such a table would provide greater flexibility in accommodating future tire designs which may have different characteristics from tires now in use.

NHTSA tentatively agrees that a table would be the most effective means of stating UTQG test inflation pressures and modifies its proposal to specify reference to a new Table I of the UTQG regulation for test inflation pressures, and for determination of tire loads, for treadwear, traction, and temperature resistance tests. An additional 30-day period is provided for comment on the proposal as modified.

Interested parties should note that the traction test procedures, which the agency arrived at prior to the advent of high inflation pressure tires, now provide that all tires are to be inflated to 24 psi for testing (49 CFR 575.104 (f)(i)(B) and (D), and loaded to 85 percent of the load specified at 24 psi for the tires' size designation in Appendix A of Standard No. 109 (49 CFR 575.104(f)(2)(viii)). In the case of a tire with maximum permissible inflation pressure greater than 32 psi, this requirement could result in the tire being underinflated during testing and loaded at a weight below that typically encountered under normal conditions of use.

NHTSA believes that if test loads were determined using a table of inflation pressures such as Table III of Standard No. 109, correct inflation would be assured and test loads more closely approximating normal driving conditions achieved. For this reason, the proposal has been modified to specify a scale of inflation pressures dependent

on maximum permissible inflation pressure in place of the single required pressure of 24 psi.

A comment received from the John Deere Product Engineering Center pointed out that under the proposed procedure, the inflation pressures used for testing of metric tires would not be precisely equivalent to the pressures used for tires with inflation pressures measured in pounds per square inch (e.g., 24 psi=180 kPa). This is also true of the modified proposal outlined in this notice. However, the test procedures are intended to provide for testing of tires under conditions of normal use, rather than to assure that each tire tested is run at the identical inflation pressure regardless of design. Therefore, the agency believes that the inflation pressures stated in Table III of Standard No. 109 provide a valid basis for comparative tire testing.

Finally, in commenting on NHTSA's proposal to modify the traction test procedures to permit adjustment of candidate tire results with standard tire results obtained either before or after the candidate tire data, Goodyear stated that while it supports the principle involved, it considers the proposed two-hour time limitation to be unnecessary. Goodyear interprets NHTSA's proposal to require a candidate tire set sequence to occur either directly before or after the standard tire sequence to which it is compared.

In proposing modification of the traction test procedures, NHTSA had intended to permit more than one candidate tire test sequence to be run before and after the corresponding standard tire sequence, so long as the standard tire sequence is completed within the same specified time period as each candidate tire sequence to which it is compared. For example, a tester could take 10 measurements on Candidate A, 10 meaurements on Candidate B and then 20 standard tire measurements, using the standard tire test sequence to adjust the results of both Candidate A and Candidate B, so long as the first test run of Candidate A and the last standard tire test run occur within the specified time limit. Tests conducted by NHTSA's Office of Vehicle Safety Compliance since the issuance of the proposal, however, suggest that even under optimal conditions the test series described above cannot be completed within a two-hour period.

In view of this finding, NHTSA conducted additional testing to determine whether a three-hour period could be permitted without affecting the accuracy of the test results. The agency tested six different tire lines on asphalt and concrete, completing comparative standard tire and candidate time sequences within a period slightly in excess of three hours. The results obtained in these tests did not differ significantly from results obtained for the same tires in tests completed within a two-hour period.

NHTSA believes that, given the expanded scope of the testing permitted by the proposal, a time limitation is necessary to minimize the effect of possible changes in test conditions, such as the temperature of the test surface. Nonetheless, it appears that a three-hour test period limitation is sufficient to control the effect of such changes. NHTSA has modified the proposal to increase the permissible time limit for related standard and candidate tire test sequences to three hours, and seeks further comment on this and any other issues relevant to the proposal.

NHTSA has evaluated the proposed changes in the UTQG regulation, as modified by this notice, and has determined that these changes are not significant within the meaning of Executive Order 12044 and the Department of Transportation policies and procedures for internal review of proposals. The scope of the changes involved and the economic savings to be derived from increased testing efficiency are not sufficient to warrant preparation of a regulatory analysis.

In consideration of the foregoing, it is proposed that 49 CFR 575.104, Uniform Tire Quality Grading, be amended as follows:

§ 575.104 [Amended]

1. Section 575.104(e)(2)(ii) would be amended by substitution of the words "the applicable pressure specified in Table II of this section." in place of the words "an inflation pressure 8 pounds per square inch less than its maximum permissible inflation pressure."

2. Section 575.104(f)(2)(i)(B) and (D) would be amended by substitution of the words "the applicable pressure specified in Table I of this section." in place of the words "24 psi." in each paragraph.

3. Section 575.104(f)(2)(vii) would be amended by addition of the following sentence, at the end thereof: "The standard tire traction coefficients so determined may be used in the computation of adjusted traction coefficients for more than one candidate tire."

4. Section 575.104(f)(2)(viii) would be amended by deletion of the words "at 24 psi" and addition of the following words after the parenthetical phrase "(§ 571.109 of this chapter)": "at the applicable inflation pressure specified in Table I of this section. Candidate tire measurements may be taken either before or after the standard tire measurements used to compute the standard tire traction coefficients. Take all standard tire and candidate tire measurements used in computation of a candidate tire's adjusted traction coefficient within a single three hour period."

5. Section 575.104(g)(1) would be amended by substitution of the words "the applicable pressure specified in Table I of this section." in place of the words "2 pounds per square inch less than its maximum permissible inflation pressure."

6. Section 575.104(g)(3) would be amended by substitution of the words "the applicable pressure specified in Table I of this section." in place of the words "2 pounds per square inch less than the maximum permissible inflation pressure."

7. Section 575.104(g)(6) would be amended by substitution of the words "applicable inflation pressure specified in Table I of this section." in place of the words "inflation pressure that is 8 pounds per square inch less than the tire's maximum permissible inflation pressure."

8. Section 575.104(g)(8) would be amended by substitution of the words "the applicable pressure specified in Table I of this section." in place of the words "2 pounds per square inch less than the tire's maximum permissible inflation pressure.

9. Section 575.104 would be amended by addition of the following table at the conclusion of the text of that section:

Table I.—*Test Inflation Pressures*

Maximum permissible inflation pressure	32 lb/in²	36 lb/in²	40 lb/in²	240 kPa	280 kPa	300 kPa
Pressure to be used in tests for treadwear and traction, and in determination of tire load for temperature resistance testing	24	28	32	160	220	180
Pressure to be used for all aspects of temperature resistance testing other than testing other than determination of tire road	30	34	38	220	260	220

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must be limited not to exceed 15 pages in length. Necessary attachments may be appended to these submissions without regard to the 15 page limit. This limitation is intended to encourage commenters to detail their primary arguments in a succinct and concise fashion.

Those persons desiring to be notified upon receipt of their comments in the rulemaking docket should enclose, in the envelope with their comments, a self addressed stamped postcard. Upon receiving the comments, the docket supervisor will return the postcard by mail.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. Any claim of confidentiality must be supported by a statement demonstrating that the information falls within 5 U.S.C. section 552(b)(4), and that disclosure of the information is likely to result in substantial competitive damage; specifying the period during which the information must be withheld to avoid that damage; and showing that earlier disclosure would result in that damage. In addition, the commenter or, in the case of a corporation, a responsible corporate official authorized to speak for the corporation must certify in writing that each item for which confidential treatment is requested is in fact confidential within the meaning of section 552(b)(4) and that a diligent search has been conducted by the commenter or its employees to assure that none of the specified items has previously been disclosed or otherwise become available to the public.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking. The NHTSA will continue to file relevant material as it becomes available to the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

In view of the present need to test metric tires under the procedures of the UTQG Standards, and the similarity of the issues involved in this notice to those addressed in the previous notice of proposed rulemaking on this subject (Docket No. 25, Notice 34), the comment period for this notice is limited to 30 days.

The principal authors of this proposal are Dr. F. Cecil Brenner of the Office of Automotive Ratings and Richard J. Hipolit of the Office of Chief Counsel.

(Sec. 103, 112, 119, 201, 203; Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392, 1401, 1407, 1421, 1423); delegations of authority at 49 CFR 1.50 and 501.8)

Issued on: May 19, 1980.

Carl Nash,

Acting Associate Administrator for Rulemaking.

[FR Doc. 80-15827 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants: Notice of Withdrawal of an Expired Proposal for Listing of the Razorback Sucker

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of withdrawal of an expired proposed rule.

SUMMARY: As amended November 10, 1978, the Endangered Species Act mandates withdrawal of proposed rules to list species which have not been finalized within two years of the proposal. The amended Act also authorized a one-year suspension of all withdrawals, until November 10, 1979. The time limit has expired for the razorback sucker (*Xyrauchen texanus)* which was originally proposed for listing as Threatened without Critical Habitat on April 24, 1978 (43 FR 17375-77). The bonytail chub (*Gila elegans)* which was proposed as Endangered without Critical Habitat in the same proposal was finalized on April 23, 1980 (45 FR 27710-13). This notice constitutes the withdrawal of the razorback sucker listing proposal.

FOR FURTHER INFORMATION CONTACT: Mr. John L. Spinks, Jr., Chief, Office of Engandered Species, Fish and Wildlife Service, Washington, D.C. 20240 (703/235-2771).

SUPPLEMENTARY INFORMATION:

Background

Section 4(f)(5) of the Endangered Species Act of 1973, as amended November 10, 1978, States that:

A final regulation adding a species to any list published pursuant to subsection (c) shall be published in the Federal Register not later than two years after the date of publication of notice of the regulation proposing listing under paragrapn (B)(i)(1). If a final regulation is not adopted with such two year period, the Secretary shall withdraw the proposed regulation and shall publish notice of such withdrawal in the Federal Register not later than 30 days after end of such period. The Secretary shall not propose a regulation adding to such a list any species for which a proposed regulation has been withdrawn under this paragraph unless he determines that sufficient new information is available to warrant the proposal of a regulation. No proposed regulation for the listing of any species published before the date of the Endangered Species Act Amendments of 1978 shall be withdrawn under this paragraph before the end of the one-year period beginning on such date of enactment.

The two-year time limit on proposals and one-year period on suspension of withdrawals which were established in this subsection have expired for the razorback sucker which was proposed April 24, 1978 (43 FR 17375-77). The razorback sucker was known to occur in the rivers of the Colorado River basin.

In accord with section 4(f)(5), the razorback sucker was withdrawn on April 24, 1980. This action gives notice of the withdrawal of this species which was known from the states of Arizona, California, Colorado, Nevada, Utah and Wyoming.

This notice is issued under the authority contained in the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.: 87 Stat. 884, 92 Stat. 3751).

The primary author of this notice is Dr. James D. Williams, Office of Endangered Species, U.S. Fish and Wildlife Service, Washington, D.C. 20240 (703/235-1975).

Dated: May 16, 1980.

Galen Buterbaugh,

Acting Director, Fish and Wildlife Service.

[FR Doc. 80-15974 Filed 5-23-80; 8:45 am]

BILLING CODE 4310-55-M

Notices

Federal Register
Vol. 45, No. 103
Tuesday, May 27, 1980

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Public Information Meeting

Notice is hereby given that the public information meeting scheduled by the Advisory Council on Historic Preservation for May 13, 1980, in Petersburg, Virginia, to discuss the proposed Hickory Hill Public Housing project and the affects to the Petersburg National Battlefield, a property included in the National Register of Historic Places, has been rescheduled to allow a minimum of 15 days notice of the public. Original notice of the meeting appeared in the Federal Register on Monday, May 5, 1980, [Vol. 45, No. 88, P. 29613].

Pursuant to Section 800.6(b)(3) of the Council's regulations, "Protection of Historic and Cultural Properties" (36 CFR Part 800), the meeting is rescheduled for June 9, 1980, at 7 p.m., at the Petersburg Redevelopment and Housing Authority, Sycamore Towers, 128 South Sycamore Street, Petersburg, Virginia.

The meeting is being called by the Executive Director of the Council in accordance with Section 800.6(b)(3) of the Council's regulations. The purpose of the meeting is to provide an opportunity for representatives of national, State, and local units of government, representatives of public an private organizations, and interested citizens to receive information and express their views concerning the proposed Hickory Hill Road Public Housing project, an undertaking of the Department of Housing and Urban Development (HUD), that will adversely affect the Petersburg National Battlefield, Petersburg, Virginia, a property included in the National Register of Historic Places. Consideration will be given to the undertaking, its effects on the National Register or eligible properties and alternate courses of action that would avoid, mitigate, or minimize any adverse effects on the Historic such properties.

The following is a summary of the agenda of the meeting.

I. An explanation of the procedures and purpose of the meeting by a representative of the Executive Director of the Council.

II. A description of the undertaking and an evaluation of its effects on the property by HUD.

III. A statement by the Virginia State Historic Preservation Officer.

IV. Statements from local officials, private organizations and the public on the effects of the undertaking on property.

V. A general question period.

Speakers should limit their statement to 5 minutes. Written statements in furtherance of oral remarks will be accepted by the Council at the time of the meeting. Additional information regarding the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1522 K Street, NW., Washington, D.C. 20005; 202-254-3495 (Attention: Charlene Dwin).

Dated: May 20, 1980.

John D. McDermott,

Acting Executive Director.

[FR Doc. 80-15834 Filed 5-23-80; 8:45 am]

BILLING CODE 4310-10-M

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

Statement of Mission; Food Quality Assurance Division

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Notice of statement of mission.

SUMMARY: This notice announces the mission of the Food Quality Assurance Division of the Food Safety and Quality Service. The effect of this document is to notify other Federal agencies, the food industry and interested parties of the mission of the Food Quality Assurance Division.

EFFECTIVE DATE: May 23, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. John M. Wyatt, Director, Food Quality Assurance Division, Commodity Services Program, Food Safety and Quality Service, Department of Agriculture, Washington, D.C. 20250, (202) 447-8582.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 1977, the Administrator for Federal Procurement Policy in the Office of Management and Budget approved an Executive Branch Plan for the Government-wide Food Quality Assurance Program for food procured by Federal agencies. The need for this program had been identified by the Commission on Government Procurement in 1972 because of the complexity of Federal food specifications, their tendency to limit competition and increase processing and distribution costs, and the fragmentation that existed because responsibility for administering inspection requirements was located in several agencies. The Secretary of Agriculture accepted responsibility for implementing the plan and subsequently assigned responsibility for the Government-wide Food Quality Assurance Program to the Food Safety and Quality Service. The Administrator, Food Safety and Quality Service, in turn, has assigned these responsibilities to the Food Quality Assurance Division.

Statement of Mission

1. Mission

The mission of the Food Quality Assurance Division is to manage and approve Federal standardization documents in Federal Supply Group 89-Food, and to establish quality assurance policies and procedures applicable to the procurement of food by Federal agencies using appropriated funds. Federal standardization documents refer to any documents used to describe the technical characteristics of food items which are applicable in the procurement of food by Federal agencies and include Federal standards and specifications, commercial item descriptions as well as all waivers, deviations and amendments to these documents.

2. Authorities

The authorities for the Food Quality Assurance Division to carry out its Government-wide responsibilities are contained in the following documents:

(a) Memorandum of July 29, 1977: Quality Assurance in the Procurement of Food by Federal Agencies; from the Administrator for Federal Procurement Policy, Office of Management and Budget, to Federal agency heads.

(b) Federal Register Notice: Delegation of Authority to the Secretary of Agriculture; 44 FR 56401, October 1, 1979.

(c) Memorandum of July 18, 1979: Government-wide Food Quality Assurance; from the Secretary of Agriculture to heads of Department agencies.

(d) Memorandum of September 28, 1979: Government-wide Food Quality Assurance; from the Administrator of the Food Safety and Quality Service, U.S. Department of Agriculture, to Agency directors.

3. Policies and Procedures

The policies and procedures related to the Government-wide management responsibilities of the Food Quality Assurance Division are being developed and will be promulgated in the near future. In the interim, all requests for food specification development, revision and approval, as well as questions concerning food quality assurance policies and procedures, should be addressed to Mr. John M. Wyatt, Director, Food Quality Assurance Division, Commodity Services Program, Food Safety and Quality Service, U.S.Department of Agriculture, Washington, D.C. 20250, (202) 447-8582.

Done at Washington, D.C., on May 21, 1980.

Donald L. Houston,

Administrator, Food Safety and Quality Service.

[FR Doc. 80-16152 Filed 5-23-80; 8:45 am]

BILLING CODE 3410-DM-M

Forest Service

Chugach National Forest, Upper Trail Lake Hatchery Project, Moose Pass, Alaska; Finding of No Signficant Impact

An environmental assessment that discusses proposed hatchery development on land adjacent to Upper Trail Lake is available for public review in the Forest Service offices in Anchorage and Seward, Alaska.

Based on the analysis and evaluation described in the environmental assessment, it is my decision to adopt Alternative 1. This alternative calls for issuance of a Special Use Permit for construction and operation of hatchery and rearing facilities at Upper Trail Lake. The site selected for this alternative is the result of feasibility studies of six different potential sites. The other alternative considered was no action. The assessement identifies the site-specific design and construction necessary to implement the project.

The District Ranger (RMA) is directed to monitor the construction and operation of the project to insure compliance with the Special Use Permit. A series of five design concepts were developed to evaluate the best means of minimizing adverse environmental effects.

The project design described in Alternative 1 provides the best combination of physical, biological, social, and economic benefits and is considered to be the environmentally preferable alternative.

I have determined that this is not a major Federal action that would significantly affect the quality of the human environment: Therefore an environmental impact statement is not needed. This determination was made considering the following factors:

(a) The majority of the project is on land approved by the Forest Service for State selection;

(b) Only the well sites may be located on National Forest land;

(c) Construction of the well sites has only slight effect on the ecosystem;

(d) There are no irreversible resource commitments;

(e) There are no apparent adverse cumulative or secondary effects.

(f) The physical and biological effects are limited to the area of planned development and use;

(g) No known threatened or endangered plants or animals are within the affected area.

Project implementation will take place upon issuance of the Special Use Permit.

This decision is subject to administrative review (appeal) pursuant to 36 CFR 211.19.

Dated: April 24, 1980.

Clay G. Beal,

Forest Supervisor.

[FR Doc. 80-15937 Filed 5-23-80; 8:45 am]

BILLING CODE 3410-11-M

Soil Conservation Service

Driftway Public Water-Based Recreation and Fish and Wildlife Development R.C. & D. Measure, Mass.

AGENCY: Soil Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of a Finding of No Significant Impact.

FOR FURTHER INFORMATION CONTACT: Mr. Sherman L. Lewis, State Conservationist, Soil Conservation Service, 29 Cottage Street, Amherst, Massachusetts 01002, telephone 413-549-0650.

NOTICE: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Driftway Public Water-Based Recreation and Fish and Wildlife Development R.C. & D. Measure, Plymouth County, Massachusetts.

The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Sherman L. Lewis, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The measure concerns a plan for development of public water-based recreation and fish and wildlife facilities. The planned works of improvement include installation of a parking lot, comfort station, picnic shelter, random picnic tables, and associated facilities; removal of the abandoned sand and gravel screening tower and a dilapidated barge pier; installation of an observation tower; construction of a fishing pier; placement of rock riprap to reinforce the existing vertical board cribbing; upgrading 5,200 feet of existing trail for pedestrian use; abandonment and seeding of 1,800 feet of former vehicular trails; improvement of about 3,600 feet of trail by suppressing poison ivy, light grading, installation of erosion control features, and surfacing with wood chips or gravel; installation of a 1-acre playing field and a roadside barrier; installation of a gravel ramp and walkway to facilitate launching nonpower boats; placement of topsoil and grass planting on about 3 acres; and planting of salt tolerant grasses on about one-fourth acre subject to tidal flooding.

The Notice of a Finding of No Significant Impact (FNSI) has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Sherman L. Lewis, State Conservationist, Soil Conservation Service, 29 Cottage Street, Amherst, Massachusetts 01002, telephone 413-549-0650. The FNSI has been sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the FNSI are available to fill single copy requests at the above address.

Implementation of the proposal will not be initiated until 30 days after the date of this publication.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program—Public Law 87-703, 16 U.S.C. 590a-f, q.)

Dated: May 13, 1980.

Joseph W. Haas,

Deputy Chief for Natural Resource Projects, Soil Conservation Service.

[FR Doc. 80-15938 Filed 5-23-80; 8:45 am]

BILLING CODE 3410-16-M

COMMISSION ON CIVIL RIGHTS

Indiana Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a factfinding meeting of the Indiana Advisory Committee (SAC) of the Commission will convene at 9:00 a.m. and end at 5:30 p.m., on June 19, 1980; also will convene at 9:00 a.m. and end at 3:00 p.m. on June 20, 1980, at City-County Building, Third Floor Council Chambers, Indianapolis, Indiana 46204.

Persons wishing to attend this open meeting should contact the Committee Chairperson or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32nd Floor, Chicago, Illinois 60604.

The purpose of this meeting is factfinding on unemployment and underemployment of minorities and women in Consolidated Uni Gov.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., May 21, 1980.

Thomas L. Neumann,

Advisory Committee Management Officer.

[FR Doc. 80-16006 Filed 5-23-80; 8:45 am]

BILLING CODE 6335-01-M

South Dakota Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a conference of the South Dakota Advisory Committee (SAC) to the Commission will convene at 4:00 p.m. on June 8 and will end at 4:30 p.m. on June 10, 1980, at Sylvan Lake Resort, P.O. Box 752, Custer State Park, South Dakota 57730.

Persons wishing to attend this conference should contact the Committee Chairperson or the Rocky Mountain Regional Office of the Commission, Executive Tower Inn, Suite 1700, 1405 Curtis Street, Denver, Colorado 80202.

The purpose of this conference is civil rights issues in the 1980's.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C. May 21, 1980.

Thomas L. Neumann,

Advisory Committee Management Officer.

[FR Doc. 80-16007 Filed 5-23-80; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Numerically Controlled Machine Tool Technical Advisory Committee; Partially Closed Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. (1976), notice is hereby given that a meeting of the Numerically Controlled Machine Tool Technical Advisory Committee will be held on Tuesday, June 10, 1980, at 10:00 a.m. in Room 5611, Main Commerce Building, 14th Street and Constitution Avenue, N.W., Washington, D.C.

The Numerially Controlled Machine Tool Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, January 13, 1977, and August 28, 1978, the Assistant Secretary for Administration approved the recharter and extension of the Committee, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and the Federal Advisory Committee Act.

The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production of technology, (C) licensing procedures which affect the level of export controls applicable to numerically controlled machine tools, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls.

The Committee meeting agenda as five parts:

General Session

(1) Opening remarks by the Chairman.

(2) Presentation of papers or comments by the public.

(3) New business.

(4) Continuation of discussion pertaining to robots and robots controls. These discussions will be supported by presentations and involvement of industry and government experts in robotics who have been invited to participate.

Executive Session

(5) Discussion of matters properly classified under Executive Order 11652, or 12065, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (5), the Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on September 6, 1978 pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in the Sunshine Act, Pub. L. 94-409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1). Such matters are specifically authorized under criteria established by an Executive Order to be kept secret in the interests of the national defense or foreign policy. All materials to be reviewed and discussed by the Committee during the Executive Session of the meeting have been properly classified under Executive Order 11652 or 12065. All Committee members have appropriate security clearances.

The complete Notice of Determination to close meetings or portions thereof of the series of meetings of the Numerically Controlled Machine Tool Technical Advisory Committee and of any Subcommittees thereof, was published in the Federal Register on October 25, 1978 (43 FR 49828).

Copies of the minutes of the General Session will be available by calling Mrs. Margaret Cornejo, Policy Planning Division, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, telephone: 202-377-2583.

For further information contact Mrs. Cornejo either in writing or by phone at the address or number shown above.

Dated: May 21, 1980.

Kent N. Knowles,

Director, Office of Export Administration, U.S. Department of Commerce.

[FR Doc. 80-16008 Filed 5-23-80; 8:45 am]

BILLING CODE 3510-25-M

CONSUMER PRODUCT SAFETY COMMISSION

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1500-7; OPTS-61005B]

Workshop on Substitutes for Asbestos; Meeting

AGENCIES: Consumer Product Safety Commission and Environmental Protection Agency.

ACTION: Notice of A Workshop on Substitutes for Asbestos.

SUMMARY: The Environmental Protection Agency (EPA) and the Consumer Product Safety Commission (CPSC) will sponsor a Workshop on Substitutes for Asbestos from July 14–16, 1980. The workshop will be held at the Sheraton National Hotel, 900 S. Orme Street, Arlington, Virginia. There is no charge for admission to this workshop.

FOR REGISTRATION INFORMATION CONTACT:

John B. Ritch, Jr., Industry Assistance Office (TS–799), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, Toll-free: 800–424–9065, In Washington, D.C.: 544–1404.

FOR TECHNICAL INFORMATION CONTACT:

Hope Pillsbury, Workshop Coordinator (TS–794), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, 202–755–8023.

SUPPLEMENTARY INFORMATION: The purpose of the workshop is to help EPA and CPSC gather information on the current technical and economic issues and potential health hazards relating to substitutes for asbestos and asbestos-containing products. The workshop will be structured so that participants may choose to attend the entire workshop, the technical/economic portion, the health portion, or individual sessions. Participants from industry, academia, government, organized labor, and public interest groups, as well as other interested parties are invited to attend.

At the outset of the workshop, overview talks on technical, economic and regulatory aspects of asbestos substitutes will be presented. These talks will include subjects such as factors affecting speed of technological innovation, problems of market definition, and the regulatory status of asbestos.

The main body of the technical/economic portion of the workshop will consist of talks on substitutes for the approximately ten asbestos product categories, followed by discussion sessions. There also will be opportunities to discuss broader issues such as the ability of substitute products to meet new or currently existing performance standards.

The second portion of the workshop will focus on health effects of both fibrous and nonfibrous types of substitutes. An overview talk on routes of exposure will be given, followed by talks on epidemiologic and experimental studies that have been made on the various substances that can be used as substitutes for asbestos. Discussion sessions will be included on the agenda.

A session is planned in which manufacturers and other experts on substitutes can inform the two Agencies about the characteristics of products that they make or have studied.

Persons who register by early June 1980 will receive a background information packet prior to the workshop to help them prepare for it.

Dated: May 14, 1980.

Steven D. Jellinek,

Assistant Administrator Office of Pesticides and Toxic Substances, Environmental Protection Agency.

Dated: May 19, 1980.

Dr. Peter W. Preuss,

Deputy Associate Executive Director, Health Sciences, Consumer Product Safety Commission.

[FR Doc. 80-15954 Filed 5-23-80; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF ENERGY

Compliance With the National Environmental Policy Act (NEPA); Intent To Prepare Environmental Impact Statement

AGENCY: Department of Energy.

ACTION: Notice of intent to prepare an environmental impact statement (EIS) for the decommissioning of the government-owned portion of the Shippingport Atomic Power Station in Beaver County, Pennsylvania.

SUMMARY: The Department of Energy (DOE) announces its intent to prepare an EIS to assess the environmental implications of a proposed DOE action to decommission the government-owned portion of the Shippingport Atomic Power Station in Beaver County, Pennsylvania.

Interested agencies, organizations, and the general public desiring to submit comments or suggestions for consideration in connection with the preparation of this EIS are invited to do so. DOE will consider the need for a public scoping meeting based on the written comments received in response to this notice. Upon completion of the draft EIS, its availability will be announced in the Federal Register, at which time comments will be solicited.

ADDRESSES: Written comments may be submitted to: R. W. Ramsey Jr., Remedial Actions Program Staff Office, Mail Station B–107, GTN, U.S. Department of Energy, Washington, D.C. 20545 (301) 353–5272.

For general information on the NEPA process, contact: NEPA Affairs Division, Office of the Assistant Secretary for Environment, U.S. Department of Energy, Attention: Richard Smith, Room 4G–064, 1000 Independence Avenue, SW., Washington, D.C. 20585 (202) 252–4600.

DATES: Written comments are due on or before June 26, 1980.

BACKGROUND INFORMATION: The Shippingport Atomic Power Station is a pressurized water reactor (PWR) electrical generating station located in a rural area about 30 miles northwest of Pittsburgh, Pennsylvania, The facilities at the Shippingport Atomic Power Station include the nuclear reactor systems, steam systems, electrical power generation equipment and miscellaneous support buildings and systems.

The site is owned by Duquesne Light Company (DLC) and leased to DOE. The reactor plant is owned by DOE and DLC owns the turbine generator portion of the station. Since initial operation in 1957, the station has supplied power to the DLC system in addition to providing technology which has served as a basis for the development of pressurized water reactors in the United States.

Since 1977, the Shippingport Atomic Power Station has been operating with a Light Water Breeder Reactor (LWBR) Core to provide the technical feasibility of the breeder concept in a light water reactor system and thereby make the LWBR technology available. The LWBR Program Environmental Statement (ERDA–1541, June 1976) covered all environmental aspects of operation in, and removal of, the LWBR Core from the Shippingport Atomic Power Station. There are no plans for further operation following removal of the LWBR Core.

The proposed action is to decommission the Shippingport Atomic Power Station reactor by one of several possible alternatives. The principal

purpose of decommissioning any nuclear facility is to effectively remove or to isolate the radioactivity associated with the facility from the environment of man. The decommissioning alternatives include no new action, prompt dismantlement, safe storage followed by dismantlement and entombment. No new action means to maintain the reactor in a shutdown and defueled condition with ongoing surveillance and maintenance. Prompt dismantlement means to disassemble, remove and dispose of all radioactive equipment, structures and materials as soon as possible after the reactor core has been removed, leaving all remaining structures and the site available for unrestricted use. Safe storage followed by dismantlement means to secure the reactor against intrusion and radiation leakage for several decades and to dismantle it after a substantial portion of the short-lived radiation has decayed. The safe storage period would require surveillance, radiation monitoring, and maintenance. Entombment means to encase the reactor and its radioactivity by means of massive concrete and steel barriers for an indefinite period of time. Entombment would require remote surveillance, remote radiation monitoring, and periodic maintenance of the entombed structure. Based on currently available information, the preferred alternative is prompt dismantling.

Impacts to be assessed for each decommissioning alternative include commitment of resources, occupational and public radiation exposure due to decommissioning activities, and radioactive waste transportation and disposal. Persons receiving routine or accidental occupational radiation exposures include surveillance and maintenance staff, if any, in addition to the actual personnel taking the decommissioning action. The impacts of contaminated liquids, vapors, gases or dust that could be released to the public during normal decommissioning operations and potential accidental incidents will be assessed. The impacts of transporting decommissioning wastes which could involve exposure of the public to additional radiation, including possible accidental radiation doses also will be assessed. Long-term and short-term non-occupational radiological effects from waste disposal involved in each alternative will be examined. Primary resources associated with the decommissioning project such as alternate land uses, aesthetic impacts, and effects on the job market and the local economy in general will be addressed. Also considered will be the effects of energy utilized during the decommissioning operations.

A draft EIS will be prepared and made available for review and comment by agencies and the public. The completion of the draft statement is tentatively scheduled for December 1980. Comments on the draft EIS will be considered in preparing the final EIS.

DOE invites agencies and individuals with special expertise or interest, and persons who may be affected by the proposed action, to participate in scoping the draft EIS. Scoping consists of identifying issues, including decommissioning alternatives and environmental impacts to be assessed in the EIS. Written comments, suggestions, and information are welcome. Comments are also solicited regarding the need for a public scoping meeting.

If it is deemed necessary to hold a public scoping meeting, a place, date, and time will be selected and advance notice provided. At such a meeting, interested persons or agencies will be invited to submit written or oral comments.

Comments and requests for information on the proposed project should be submitted to R. W. Ramsey, Jr. at the above address, and those seeking further information on the NEPA process should inquire with the NEPA Affairs Division at the above address. Those not desiring to submit comments or suggestions at this time, but who would like to receive a copy of the draft EIS for review and comment when it is issued, should also contact Mr. Ramsey. Copies of ERDA-1541 and reports used in the preliminary assessment of environmental effects of the proposed project and a bibliography of the other documents currently planned to be used in the preparation of the draft EIS are available for public inspection at the following locations.

B. F. Jones Memorial Library, 663 Franklin Place, Aliquippa, Pennsylvania 15001
Carnegie Library of Pittsburgh, 440 Forbes Avenue, Pittsburgh, Pennsylvania 15213
Department of Energy, Public Reading Room, Room 6A-152, 1000 Independence Avenue, SW, Washington, D.C. 20585.

Copies of all comment letters received in response to this notice will be available for public inspection at the above locations.

In addition, the bibliography will be available for public inspection at:

Albuquerque Operations Office, National Atomic Museum, Kirtland Air Force Base East
Chicago Operations Office, 9800 South Cass Avenue, Argonne, Illinois
Idaho Operations Office, 550 Second Street, Idaho Falls, Idaho
Nevada Operations Office, 2753 South Highland Drive, Las Vegas, Nevada
Oak Ridge Operations Office, Federal Building, Oak Ridge, Tennessee
Richland Operations Office, Federal Building, Richland, Washington
Savannah River Operations Office, Savannah River Plant, Aiken, South Carolina.

All suggestions, comments and questions submitted to R. W. Ramsey, Jr. prior to the close of the comment period will be fully considered in the preparation of the draft EIS.

Dated at Washington, D.C., this 15th day of May, 1980.

For the United States Department of Energy.

Ruth C. Clusen,

Assistant Secretary for Environment.

[FR Doc. 80-16005 Filed 5-23-80; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

Delta Petroleum Corp.; Petition for Permission To Use Multiple Allocation Fractions

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of petition and request for comments.

SUMMARY: The Economic Regulatory Administration of the Department of Energy hereby gives notice that, on March 14, 1980, Delta Petroleum Corporation (Delta), in accordance with the provisions of 10 CFR 205.90 *et seq.* and § 211.10(b), filed a petition for permission to use multiple allocation fractions. The relief, if granted, would permit Delta to use one allocation fraction for the sale of motor gasoline to its customers in Okeechobee, Florida, and a separate allocation fraction for customers in Dade, Broward, and Palm Beach counties.

A copy of Delta's application, with proprietary material deleted, may be examined between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, at the Economic Regulatory Administration, Office of Petroleum Operations, Room 6222-C, 2000 M Street, N.W., Washington, D.C.

DATE: Comments on or before June 6, 1980.

ADDRESS: Send comments to: Economic Regulatory Administration, Office of Petroleum Operations, Room 6222, 2000 M Street, NW., Washington, D.C. 20461. Attn: Alan T. Lockard.

FOR FURTHER INFORMATION CONTACT:

John A. Carlyle, Economic Regulatory Administration, Office of Petroleum Operations, Room 6222-C, 2000 M

Street, NW., Washington, D.C. 20461, Telephone: (202) 653-3431.

Joel M. Yudson, Office of the General Counsel, Room 6A-127, 1000 Independence Avenue, SW., Washington, D.C. 20585, Telephone: (202) 252-6744.

Issued in Washington, D.C., on the 19th day of May 1980.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 80-16003 Filed 5-23-80; 8:45 am]

BILLING CODE 6450-01-M

Proposed Remedial Orders

Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration of the Department of Energy hereby gives Notice that the following Proposed Remedial Orders have been issued. These Proposed Remedial Orders allege violations of the Mandatory Petroleum Price Regulations.

A copy of the Proposed Remedial Orders, with confidential information deleted, may be obtained from Thomas Holleran, Program Manager for Product Retailers, 2000 M Street, NW, Washington, DC 20461, phone 202/653-3569. On or before June 11, 1980. Any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, 2000 M Street, NW, Washington, DC 20461, in accordance with 10 CFR § 205.193.

Issued in Washington, D.C., on the 19th day of May 1980.

Robert D. Gerring,

Director, Enforcement Program Operations Division, Economic Regulatory Administration.

Northeast District: PRO's

Firm name and address	Audit date	Violation amount	Highest cents per gallon violation
Rodbern Service Station, 665 Peninsula Boulevard, Hempstead, NY 11550	2/28/80	$3,314	.023
Twin Parks Service Station, 2103 Webster Avenue, Bronx, NY 10457	2/29/80	3,345	.062

Southwest District: PRO's

Firm name and address	Audit date	Violation amount	Highest cents per gallon violation
Bert's Phillips 66, 325 South Second, Stillwell, OK 74960	4/17/80	$4,515.05	11.8

Western District: PRO's

Firm name and address	Audit date	Violation amount	Highest cents per gallon violation
Shamuel Lazar, Lazar Super Shell, 377 6th Street, San Francisco, CA 94103	1/11/80	$5,616.31	.051
Mike Keegan, Mike's Shell Service, 1201 Harrison Street, San Francisco, CA 94103	1/11/80	1,610.78	.060
Allen Person, 10th Street Chevron, 7000 Monterey, Gilroy, CA 95020	1/29/80	10,596.56	.081
Ed Gularte Chevron, 131 N. Main, Salinas, CA 93901	1/30/80	9,309.70	.097
Bob Hutchinson, Inc., 2200 Telegraph Avenue, Oakland, CA 94612	1/3/80	2,439.59	.063
Khosroin Hifai, Ray's Civic Center Mobil, 1271 No. First Street, San Jose, CA 95112	1/4/80	5,041.68	.119
Chuck's Auto Service, 2101 N. 1st Street, San Jose, CA 95131	1/4/80	2,421.70	.079
Larry Septon, Alameda Chevron, 955 Alameda, San Jose, CA 95126	1/4/80	1,869.31	.068
Walt Jost, Walt Shell Service, 16601 Alamanden, San Jose, CA 95120	1/3/80	7,121.60	.082
Jim Lutz, Petaluma Standard Service, 1440 E. Washington, Petaluma, CA 94952	8/20/79	3,987.27	.029
Milton Paige, Westlake Union, 101 South Mayfair, Daly City, CA 94015	8/20/79	1,618.29	.053
Conn Ward, Millbrae Shell, 500 Broadway Street, Millbrae, CA 94030	1/30/80	3,906.47	.061
Dhority's Union 76, 1600 Mission Street, San Francisco, CA 94103	8/15/79	2,919.46	.059
Bob Walitsch, Miraloma Shell, 701 Portola Avenue, San Francisco, CA 94127	8/15/79	4,159.71	.060
Gallagher's Shell, 111 El Camino Real, San Bruno, CA 94066	1/30/80	1,837.15	.060
Ken's Chevron, 375 Cabrillo Highway, Half Moon Bay, CA 94019	1/30/80	14,398.84	.097
Weber's Chevron Service, 7719 Soquel Drive, Aptos CA 95003	1/4/80	11,776.96	.097
Steve Horner, dba Steve Horner Chevron, 3500 Lakeshore Avenue, Oakland, CA 94610	1/3/80	5,161.54	.072
Peter Marenco Phillips, 1700 Sonoma Blvd., Vallejo, CA	2/28/80	4,387.42	.107
Valle Vista Chevron (Frank Terrasas), 3288 Sonoma Blvd., Vallejo, CA 94590	1/30/80	4,929.50	.061
Bill Pendergast & Sons Chevron, 4375 Sonoma Blvd., Vallejo, CA 94590	1/30/80	8,834	.089
B & M Texaco & Towing, Lathrop Road and Highway 99, Manteca, CA 95336	4/09/80	2,966.68	.074
Larry Septon, Berryessa Chevron, 1715 Berryessa Road, San Jose, CA 95133	1/4/80	3,864.00	.071
George Cravines, Circle Service, 2901 Sneath Lane, San Bruno, CA 94066	1/3/80	2,505.60	.054
Benjamin Marshall, Ben's Exxon Service, 925 Cutting Boulevard, Richmond, CA 94804	1/10/80	4,533.73	.088
Jack Jung, Cutting Shell Service, 1000 Cutting Blvd., Richmond, CA 94804	1/10/80	7,135.62	.067
Ted's Arco, Ted Lampros, 2095 19th Avenue, San Francisco, CA 94116	12/3/79	2,168.16	.070
Bill Dobko Chevron, 3139 Jefferson Avenue, Redwood City, CA 94062	8/31/79	299.13	.034

Western District: PRO's—Continued

Firm name and address	Audit date	Violation amount	Highest cents per gallon violation
Gray Goodnough, Gateway Texaco, 1036 N. Rengstoff, Mountain View, CA 94043	9/13/79	1,266.45	.057
Bill Wren's Shell, 1200 19th Avenue, San Francisco, CA 94107	12/03/79	6,518.63	.053
Wallace Arco, 5898 Mission Street, San Francisco, CA 94112	12/10/79	1,778.14	.051
Regalia's Chevron Service, Kenneth Regalia, 1201 Tara Hills Drive, Pinole, CA 94564	1/11/80	8,865.26	.073
Joe Berube Services, 13052 San Pablo Avenue, San Pablo, CA 94806	1/11/80	8,282.94	.084
Ronald W. Mosiniak, Ron's Shell, 140 Produce, So. San Francisco, CA 94080	9/13/79	1,541.03	.064
Redman Service, Inc., 9732 Santa Monica Blvd., Beverly Hills, CA 90210	4/07/80	2,558.04	.032

[FR Doc. 80-16004 Filed 5-23-80; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1500-6; OPTS—59023]

Proctor Chemical Co., Inc.; Premanufacture Exemption Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1)(A) of the Toxic Substances Control Act (TSCA) requires any person intending to manufacture or import a new chemical substance for a commercial purpose in the United States to submit a premanufacture notice (PMN) to EPA at least 90 days before he commences such manufacture or import. Under section 5(h) the Agency may, upon application, exempt any person from any requirement of section 5 to permit such person to manufacture or process a chemical for test marketing purposes. Section 5(h)(6) requires EPA issue a notice of receipt of any such application for publication in the Federal Register. This notice announces receipt of an application for an exemption from the premanufacture reporting requirements for test marketing purposes and requests comments on the appropriateness of granting the exemption.

DATES: The Agency must either approve or deny this application by June 15, 1980. Persons should submit written comments on the application no later than June 11, 1980.

ADDRESS: Written comments to: Document Control Officer (TS-793), Office of Pesticides and Toxic

Substances, Environmental Protection Agency, 401 M St. SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Radosevich, Premanufacturing Review Division (TS–794), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460, (202–426–2601).

SUPPLEMENTARY INFORMATION: Under section 5 of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice to EPA before manufacture or import begins. A "new" chemical substance is any chemical substance that is not on the Inventory of existing chemical substance compiled by EPA under section 8(b) of TSCA. EPA first published the Initial Inventory on June 1, 1979. Notice of availability of the Inital Inventory was published in the Federal Register on May 15, 1979 (44 FR 28558). The requirement to submit a PMN for new chemical substances manufactured or imported for commercial purposes became effective on July 1, 1979.

Section 5(a)(1) requires each PMN to be submitted in accordance with section 5(d) and any applicable requirement of section 5(b). Section 5(d)(1) defines the contents of a PMN. Section 5(b)(1) contains additional reporting requirements for chemical substances that are subject to testing rules under section 4. Section 5(b)(2) requires additional information in PMN's fur substances which EPA, by rules under section 5(b)(4), has determined may present unreasonable risks of injury to health or the environment.

Section 5(h), "Exemptions," contains several provisions for exemptions from some or all of the requirements of section 5. In particular, section 5(h)(1) authorizes EPA, upon application, to exempt persons from any requirement of section 5(a) or section 5(b) to permit the persons to manufacture or process a chemical substance for test marketing purposes. To grant such an exemption, the Agency must find that the test marketing activities will not present any unreasonable risk of injury to health or the environment. EPA must either approve or deny the application within 45 days of its receipt, and the Agency must publish a notice of its disposition in the Federal Register. If EPA grants a test marketing exemption, it may impose restrictions on the test marketing activities.

Under section 5(h)(6), EPA must publish in the Federal Register a notice of receipt of an application under section 5(h)(1) immediately after the Agency receives the application. The notice identifies and briefly describes the application (subject to section 14 confidentiality restrictions) and gives interested persons an opportunity to comment on it and whether EPA should grant the exemption. Because the Agency must act on the application within 45 days, interested persons should provide comments within 15 days after the notice appears in the Federal Register.

EPA has proposed Premanufacture Notification Requirements and Review Procedures published in the Federal Register of January 10, 1979 (44 FR 2242) and October 16, 1979 (44 FR 59764) containing proposed premanufacture rules and notice forms. Proposed 40 CFR 720.15 (44 FR 2268) would implement section 5(h)(1) concerning exemptions for test marketing and includes proposed 40 CFR 720.15(c) concerning the section 5(h)(6) Federal Register notice. However, these requirements are not yet in effect. In the meantime, EPA has published a statement of Interim Policy published in the Federal Register of May 15, 1979 (44 FR 28564) which applies to PMN's submitted prior to promulgation of the rules and notice forms.

Interested persons may, on or before June 11, 1980, submit to the Document Control Officer (TS–793), Rm. E–447, Office of Pesticides and Toxic Substances, 401 M St., SW., Washington, D.C. 20460, written comments regarding this notice. Three copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the document control number "[OPTS–59023]". Comments received may be seen in the above office between 9:00 a.m. and 4:00 p.m., Monday through Friday, excluding holidays.

(Sec. 5, 90 Stat. 2012 (15 U.S.C. 2604))

Dated: May 19, 1980.

John P. Dekany,

Deputy Assistant Administrator for Chemical Control.

TM 80–23.

Close of Review Period. June 15, 1980.

Manufacturer's Identity. Proctor Chemical Co., Inc., P.O. Box 399, Salisbury, NC 28144.

Specific Chemical Identity. Carbamic acid, bis(methoxy methyl)- isopropyl ester.

The following summary is taken from data submitted by the manufacturer in the test marketing exemption.

Use. None given by the manufacturer.

Production Estimates. No more than 200 pounds will be manufactured for test marketing purposes.

Physical/Chemical Properties. Physical/Chemical properties are not known by the manufacturer.

Toxicity Data. No data are known by the submitter regarding health and environmental effects of the chemical.

Worker Exposure.

Activity	Max No. workers exposed	Max. duration of exposure
Testing marketing	50	2 hrs.

Manufacturing exposure will be limited to filtering the mixture during packaging and test marketing evaluation will involve exposure to aqueous solutions of the new chemical mixture.

The substance will be supplied in an aqueous solution and will be transferred from the shipping container to a vessel for dilution. Exposure at this point would be limited to one person. Typical industry practice for the operation of this mixing area is the wearing of gloves, apron, and safety glasses. At this point of application one or two people might come in contact with the new chemical but that should occur only if equipment fails.

[FR Doc. 80–15983 Filed 5–23–80; 8:45 am]

BILLING CODE 6560–01–M

[FRL 1500–4]

Approval of PSD Permit to M & T Chemical, Inc.

Notice is hereby given that on March 7, 1980, the Environmental Protection Agency issued a Prevention of Significant Deterioration permit PSD–KY–127 to M & T Chemical, Inc., for approval to modify their existing plant in Carrollton, Kentucky.

This federal permit to construct has been issued under EPA's Prevention of Significant Air Quality Deterioration regulations (40 CFR 52.21), subject to certain conditions, General Conditions No. 1 through 12.

Special Condition: Production of $SnCl_4$ shall be limited to not more than 1000 lb/hr (3168 TPY) from Reactor No. 1 and 1500 lb/hr (5634 TPY) from reactor No. 2.

The PSD permit is reviewable under Section 307(b)(1) of the Clean Air Act as a locally-applicable final action, if a petition for review is filed on or before July 28, 1980.

Copies of the permit are available for public inspection upon request at the following locations:

Environmental Protection Agency, Region IV, Air Facilities Branch, Room 402, 345 Courtland Street, N.E., Atlanta, Georgia 30365.

Department for Natural Resources and Environmental Protection, Division of

Air Pollution Control, West Frankfort Office Complex, 1050 U.S. 127 Bypass South, Frankfort, Kentucky 40601.

Dated: May 12, 1980.

Rebecca W. Hanmer,

Regional Administrator, Region IV.

[FR Doc. 80-15952 Filed 5-23-80; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 15712; Gen. Docket No. 80-184]

Inquiry Begun on Changes to International Radio Regulations for Mobile Services WARC

April 29, 1980.

The Commission has issued a Notice of Inquiry to solicit public comments on changes to the International Radio Regulations dealing with the Mobile Services which might be considered at a World Administrative Radio Conference (WARC).

It said it expected that the International Telecommunication Union (ITU) would hold a WARC for the Mobile Services in the next few years to review the International Radio Regulations pertaining to Distress and Safety Communications, the Aeronautical Mobile, Maritime Mobile and Maritime Mobile-Satellite, and Land Mobile Services, as well as other provisions as they applied to the Mobile Services.

Such a conference, the Commission added, also would have to prescribe, for example, the use of frequency allocations to the Mobile Services resulting from the 1979 WARC.

Therefore, the FCC said it wanted to solicit comments which the public believed should be considered by the Commission in developing its proposals for the mobile WARC.

It pointed out, however, that this proceeding was limited to the development of U.S. proposals and negotiating strategies for the conference and did not involve changes in or additions to Commission rules and regulations.

Pointing out that Appendix 4 of the Notice of Inquiry listed a number of questions that might be addressed by the United States in preparation for the Mobile Services WARC, the Commission asked that the public give its initial view on these questions and any other pertinent matters in the Articles listed which should be incorporated into the International Radio Regulations for the Mobile Services.

Comments are due June 9, 1980, replies June 30, 1980.

Action by the Commission April 24, 1980, by Notice of Inquiry (FCC 80-232). Commissioners Ferris (Chairman), Lee, Quello, Washburn, Fogarty, Brown and Jones.

This is an unofficial announcement of the Commission's action. Release of the full text of the Commission's order constitutes official action. See MCI v. FCC, 515 F. 2d 385 (D.C. Cir. 1975).

For additional information contact Lawrence Palmer, (202) 632-7093.

The text of the FCC's Notice of Inquiry has been released publicly May 15, 1980. Because of the cost of printing so voluminous a text, it will not be published in the Federal Register. However, the FCC has prepared a limited number of copies that are available upon request (Notice of Inquiry, FCC 80-232, Gen. Docket No. 80-184, adopted April 24, 1980, "Inquiry relating to preparation for an International Telecommunication Union World Administrative Radio Conference for the Mobile Services") at its Information Office, Room 202, 1919 M Street NW., Washington, D.C. 20554. The Notice of Inquiry is also available for inspection at the Commission's Docket Reference Room, or can be acquired through a copier service.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 80-15941 Filed 5-23-80; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Agreements Filed

The Federal Maritime Commission hereby gives notice that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of each of the agreements and the justifications offered therefor at the Washington Office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10218; or may inspect the agreements at the Field Offices located at New York, N.Y.; New Orleans, Louisiana; San Francisco, California; Chicago, Illinois; and San Juan, Puerto Rico. Interested parties may submit comments on each agreement, including requests for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before June 16, 1980. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should alos be forwarded to the party filing the agreements and the statement should indicate that this has been done.

Agreements Nos. 2744-44, 10390 and 10391.

Filing Party: Seymour H. Kligler, Esquire, Brauner Baron Rosenzweig Kligler, Sparber & Bauman, 120 Broadway, New York, New York 10005.

Summary: Agreements Nos. 2744-44, 10390, and 10391 will, respectively, (1) eliminate ports and points in Ecuador from the scope of the United States Atlantic and Gulf/West Coast of South America Conference; (2) establish a new conference in the trade from U.S. Atlantic and Gulf Coast ports other than those in Florida to ports and points in Ecuador; and (3) establish a new conference from ports in Florida to ports and points in Ecuador.

Agreement No. 9522-43.

Filing Party: John R. Attanasio, Attorney for the Med-Gulf Conference, 2033 K Street, N.W.—Suite 300, Washington, D.C. 20006.

Subject: Agreement No. 9522-43 would amend the Med-Gulf Conference Agreement to provide that members may agree upon the establishment of charges and other tariff conditions relating to the movement, handling and storage of empty containers and other intermodal equipment in the United states or in Continental Europe.

Agreement No. 10392.

Filing Party: Ronald C. Rasmus, President, American Atlantic Lines, One World Trade Center, Suite 1067, New York, New York 10048.

Summary: Agreement No. 10392 is a talking agreement betwen Frota Amazonica S.A. and American Atlantic Shipping, Inc. The purpose of the agreement is to examine the possibility of initiating negotiations between the parties regarding the establishment of an agreement for cargo distribution and traffic rationalization in the trade between the Brazilian Amazon Basin and the U.S. East Coast.

By Order of the Federal Maritime Commission.

Dated: May 21, 1980.

Francis C. Hurney,

Secretary.

[FR Doc. 80-16010 Filed 5-23-80; 8:45 am]

BILLING CODE 6730-01-M

United States Atlantic and Gulf/ Venezuela and Netherlands Antilles Conference (Oil Agreement); Cancellation

Agreement No. 6870.

Filing Party: Seymour H. Kligler, Brauner Baron Rosenzweig Kligler, Sparber & Bauman, 120 Broadway, New York, New York 10005.

Summary: The Commission has received notification of the cancellation of Agreement No. 6870. The cancellation is effective April 10, 1980.

By Order of the Federal Maritime Commission.

Dated: May 21, 1980.

Francis C. Hurney,

Secretary.

[FR Doc. 80-16011 Filed 5-23-80; 8:45 am]

BILLING CODE 6730-01-M

Hawaiian Marine Lines, Inc.; Application for Permission to Submit Alternative Data

The Federal Maritime Commission hereby gives notice that Hawaiian Marine Lines, Inc. (HML) has filed an application with the Commission for permission to submit alternative data pursuant to 46 CFR 512.2(d).

HML proposes to use revenue tons rather than cargo cube as the basis for allocations in submissions required by the Commission's General Order 11. HML proposes to submit its annual filing for 1979, as well as an anticipated application for a general rate increase, on this basis. Interested parties may inspect the data submitted in support of the application at the Washington Office of the Federal Maritime Commission, 1100 L Street, N.W., Washington, D.C. Interested parties may submit comments on the application to the Secretary, Federal Maritime Commission, Washington, D.C. 20573 on or before June 16, 1980. A copy of any comments should also be forwarded to HML at Post Office Box 2287, Seattle, Washington 98111, and the statements should indicate that this has been done.

Dated: May 21, 1980.

Francis C. Hurney,

Secretary.

[FR Doc. 80-15977 Filed 5-23-80; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL MEDIATION AND CONCILIATION SERVICE

Arbitration Services Advisory Committee; Meeting

Notice is hereby given that the Federal Mediation and Conciliation Service Arbitration Services Advisory Committee, in accordance with Section 10 of the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776), will meet on Saturday, June 14, 1980 at 9:00 a.m. at the Century Plaza Hotel, Los Angeles, California.

The Agenda is as follows:

I. Review of FY 1979 Caseload

II. Current FY 1980 Caseload

III. Roster of Arbitrators: Additions, Removals, Pending Actions

IV. Violations of Code of Federal Regulations: Violations of Code of Professsional Responsibility

V. Office of Arbitration Services: Staffing, Procedrues, Budget FY 1981, Classifications Audit

VI. Audit of Office of Arbitration Services by Government Accounting Office

VII. Proposed study by Ben Fischer

VIII. Report on *Special Handling* Situations: Expedited Procedures, Standing Single Issue Procedure, Strike Settlement

IX. Arbitrator Symposia and Seminars

This meeting shall be open to the public.

Communications regarding this meeting should be addressed to:
Ms. Jewell Myers, Administrator,
Office of Arbitration Services,
Federal Mediation and Conciliation Service,
Washington, D.C. 20427.

Signed at Washington, D.C., this nineteenth day of May 1980.

Wayne L. Horvitz,

Director.

[FR Doc. 80-15970 Filed 5-23-80; 8:45 am]

BILLING CODE 6732-01-M

FEDERAL RESERVE SYSTEM

American Heritage Corp.; Proposed Retention of Insurance Activities

American Heritage Corporation, Colorado Springs, Colorado, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. § 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulations Y (12 CFR 225.4(b)(2)), for permission to continue to act as agent for the sale of credit-related insurance.

Applicant states that is would engage in the activities of acting as agent for the sale of credit life and disability insurance to customers of American Heritage Bank and Trust Co. These activities would be performed from offices of Applicant in Colorado Springs, Colorado, and the geographic areas to be served are the city of Colorado Springs and the Southwestern portion of El Paso County, Colorado. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair conpetition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than June 18, 1980.

Board of Governors of the Federal Reserve System, May 20, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-16023 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Antioch Bancshares, Inc.; Formation of Bank Holding Company

Antioch Bancshares, Inc., Antioch, Illinois, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 100 percent or more of the voting shares (less directors' qualifying shares) of the successor by merger to First National Bank of Antioch, Antioch, Illinois. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than June 20, 1980. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing,

identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, May 20, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-16022 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Stockton Bancshares, Inc.; Formation of Bank Holding Company

Stockton Bancshares, Inc., Stockton, Kansas, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 99.5 percent of the voting shares of the Stockton National Bank, Stockton, Kansas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than June 19, 1980. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, May 20, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-16021 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Bank Holding Companies; Proposed De Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices." Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and, except as noted, received by the appropriate Federal Reserve Bank not later than June 18, 1980.

A. *Federal Reserve Bank of Philadelphia* (Thomas K. Desch, Vice President), 100 North 6th Street, Philadelphia, Pennsylvania 19105:

Philadelphia National Corporation, Philadelphia, Pennsylvania (commerical finance activities; United States and Puerto Rico): To engage directly in the making of loans secured by accounts receivable, inventory, equipment and other collateral and the purchase of participations in commerical finance transactions effected by approved subsidiaries of Philadelphia National Corporation. These activities would be conducted from the Corporation's principal office in Philadelphia, Pennsylvania, serving the United States and Puerto Rico.

B. *Federal Reserve Bank of San Francisco* (Harry W. Green, Vice President), 400 Sansome Street, San Francisco, California 94120:

Wells Fargo & Company, San Francisco, California (mortgage banking and insurance activities; Arizona, California, Colorado, Idaho, Montana, Nevada, Oregon, Utah, Washington, and Wyoming): To engage, through it subsidiary, Wells Fargo Mortgage Company, in making, acquiring, and servicing loans and other extensions of credit secured by real estate mortgages; and in acting as insurance agent or broker in the sale of credit life, credit accident and health, mortgage redemption life, and group mortgage disability insurance. These activities would be conducted from an office in Bend, Oregon, serving the ten states listed in the caption above. Comments on this application must be received by June 13, 1980.

C. *Other Federal Reserve Banks:* None.

Board of Governors of the Federal Reserve System, May 20, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board,

[FR Doc. 80-15966 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-10-M

The Bank of New York Co., Inc.; Proposed Acquisition of ARCS Mortgage Corp., Inc. and ARCS Mortgage, Inc.

The Bank of New York Company, Inc., New York, New York, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to acquire voting shares of ARCS Mortgage Corporation, Inc., North Miami Beach, Florida, and ARCS Mortgage, Inc., Encino, California.

Applicant states that the proposed subsidiaries would engage in mortgage banking activities. These activities would be performed from offices of ARCS Mortgage, Inc., in Cerritos, Covina, Encino, Clovis, Oxnard, Paso Robles, Sacramento, San Diego, San Jose, Stockton, Van Nuys, Hayward, and Pleasant Hill, California; and from offices of ARCS Mortgage Corporation, Inc. in West Palm Beach, Lighthouse Point, and North Miami Beach. The geographic areas to be served are the counties of Fresno, Ventura, San Luis Obispo, Sacramento, San Diego, Santa Clara, San Joaquin, Alameda, and Contra Costa, California; East San Fernando Valley, Eagle Rock, Highland Park, Simi Valley, and Los Angeles and the surrounding area, California; and Dade, Broward, and Palm Beach Counties, Florida. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of

the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of New York.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than June 19, 1980.

Board of Governors of the Federal Reserve System, May 19, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-15965 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Capital Bancshares, Inc.; Formation of Bank Holding Company

Capital Bancshares, Inc., Dallas, Texas, has applied for the Board's approval under 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares of Capital Bank, Dallas, Texas. The factors that are considered in acting on the application are set forth in 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than June 19, 1980. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, May 19, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-15962 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Carbondale Bancshares, Inc.; Formation of Bank Holding Company

Carbondale Bancshares, Inc., Carbondale, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of Mid-America Bank and Trust Company of Carbondale, Carbondale, Illinois. The factors that are considered in acting on the application are set forth section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of St. Louis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than June 16, 1980. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, May 20, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-15963 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Kit Carson Insurance Agency, Inc.; Proposed Retention of General Insurance Agency

Kit Carson Insurance Agency, Inc., Kit Carson, Colorado, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to retain its general insurance agency in Kit Carson, Colorado.

Applicant states that the proposed subsidiary would engage in general insurance agency activities. These activities would be performed from offices of Applicant's subsidiary in Kit Carson, Colorado, and the geographic area to be served is the Kit Carson, Colorado community. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than June 19, 1980.

Board of Governors of the Federal Reserve System, May 19, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-15964 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Verdigre Agency; Proposed Continuation of General Insurance Activities

The Verdigre Agency, Verdigre, Nebraska, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to continue to engage in general insurance agency activities.

These activities would be performed from offices of Applicant in Verdigre, Nebraska, and the geographic area to be served is Western Knox County, Nebraska. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increase competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the

evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than June 19, 1980.

Board of Governors of the Federal Reserve System, May 19, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-15964 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

Wyoming Bancorporation; Acquisition of Bank

Wyoming Bancorporation, Cheyenne, Wyoming, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 per cent, less directors' qualifying shares, of the voting shares of First Wyoming Bank-Worland, Worland, Wyoming. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than June 16, 1980. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, May 16, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-15960 Filed 5-23-80; 8:45 am]

BILLING CODE 6210-01-M

GENERAL ACCOUNTING OFFICE

Regulatory Reports Review; Receipt of Report Proposal

The following request for clearance of a report intended for use in collecting information from the public was received by the Regulatory Reports Review Staff, GAO, on May 19, 1980. See 44 U.S.C. 3512 (c) and (d). The purpose of publishing this notice in the Federal Register is to inform the public of such receipt.

The notice inlcudes the title of the request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed CPSC request are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed request, comments (in triplicate) must be received on or before June 16, 1980, and should be addressed to Mr. John M. Lovelady, Senior Group Director, Regulatory Reports Review, United States General Accounting Office, Room 5106, 441 G Street, NW, Washington, DC 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202-275-3532.

Consumer Product Safety Commission

The CPSC requests clearance of new regulations, Part 1019—Procedures for Export of Noncomplying Products, requiring exporters to notify the Commission at least 30 days prior to the exportation of any product which does not comply with an applicable ban, standard or regulation issued under the Consumer Product Safety Act (CPSA, 15 U.S.C. 2051 et seq.), the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261, et seq.), or the Flammable Fabrics Act (15 U.S.C. 1191, et seq.). The regulations implement the Consumer Product Safety Act Authorization Act of 1978 (Pub. L. 95-631). That act requires exporters to notify the Commission at least 30 days prior to exportation of any product which does not comply with an applicable ban, standard, or regulation under the CPSA, FHSA, or FFA. The Authorization Act of 1978 requires that the Commission must promptly transmit the information contained in the exporter's notification to the government of the country of intended destination so that the foreign government may make an informed decision about whether to admit the goods into its territory. The regulations approved by the Commission specify the types of goods which are subject to and exempt from the requirements for notification; prescribe the information to be furnished in the notification; and set forth the procedures for filing the notification. The requirements for notification set forth in the regulations will continue as long as the export provisions of the Authorization Act of 1978 remain in effect. The requirements for notification contained in the regulations are applicable only to those firms that intend to export noncomplying products. The Commission estimates that the number of firms exporting noncomplying goods will not exceed 50 per year. The information required to be furnished by the regulations is information which the exporter would have available in order to complete the export transaction CPSC states. Therefore, the Commission estimates that no more than two hours will be needed to make the notification required by the regulations. After GAO clearance the regulations will become effective within 30 days after CPSC publishes the regulations in the Federal Register.

Norman F. Heyl,

Regulatory Reports Review Officer.

[FR Doc. 80-15958 Filed 5-23-80; 8:45 am]

BILLING CODE 1610-01-M

GENERAL SERVICES ADMINISTRATION

[GSA Bulletin FPR 44]

Federal Procurement

May 12, 1980.

To: Heads of Federal agencies

Subject: New Qualified Videotape Producers List

1. *Purpose.* This bulletin announces the availability of the new Qualified Videotape Producers List (QVPL).

2. *Expiration date.* This bulletin will remain in effect until canceled or superseded.

3. *General.* Federal Procurement Regulations (FPR) Temporary Regulation 53, March 31, 1980, implements the Office of Federal Procurement Policy (OFPP) Letter No. 79-4, November 28, 1979. The policy letter establishes a Government-wide system for contracting for motion picture and videotape productions. The new Qualified Videotape Producers List was issued by the Executive Agent (designated by OFPP) on March 21, 1980. Revisions to the list will be issued on a quarterly basis. GSA Bulletin FPR 43, April 16, 1980, announced the availability of the revised Qualified Film Producers List.

4. *List of qualified concerns.* Copies of the new QVPL (attachment A) are available to all Federal agencies without charge. Requests should be submitted in writing to:

Executive Agent, Government-wide Contracting System For Audiovisual

Productions, DoD Directorate For Audiovisual Activities, 1117 North 19th Street, Room 601, Arlington, VA 22209.

Note.—Attachment A, which is referenced in paragraph 4, is filed with the original document and does not appear in this volume.

Gerald McBride,

Assistant Administrator for Acquisition Policy.

[FR Doc. 80-15986 Filed 5-23-80; 8:45 am]

BILLING CODE 6820-61-M

[F-80-7]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent, in conjunction with the Administrator of General Services, the consumer interests of the executive agencies of the Federal Government in the proceedings before the Ohio Public Utilities Commission involving intrastate telecommunications service rates.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.* a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the Ohio Public Utilities Commission involving the application of the Ohio Bell Telephone Company for increases in its rates for intrastate telecommunications services. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

Dated: May 15, 1980.

Ray Kline,

Acting Administrator of General Services.

[FR Doc. 80-15987 Filed 5-23-80; 8:45 am]

BILLING CODE 6820-25-M

[F-80-6]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent, in conjunction with the Administrator of General Services, the consumer interests of the executive agencies of the Federal Government in proceedings before the Utah Public Service Commission involving intrastate telecommunications service rates.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.* a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the Utah Public Service Commission involving the application of the Mountain States Telephone and Telegraph Company for increases in its rates for intrastate telecommunications services. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

Dated: May 15, 1980.

Ray Kline,

Acting Administrator of General Services.

[FR Doc. 80-15989 Filed 5-23-80; 8:45 am]

BILLING CODE 6820-25-M

National Archives and Records Service

National Archives and Records Service Advisory Committee on Preservation; Meeting

Notice is hereby given that the National Archives and Records Service Advisory Committee on Preservation will meet on June 19, 1980, from 9:00 a.m. to 5:00 p.m. and June 20, 1980, from 9:00 a.m. to 12:00 noon, in Room 105, National Archives and Records Service, 8th and Pennsylvania Avenue, NW., Washington, DC 20408. The meeting will be devoted to a review of the state of current preservation technology and research; preservation problems arising from the use of past technologies; potential preservation problems that may arise when records on new media are accessioned; and related matters of concern to the continued preservation of the records of the National Archives of the United States.

The meeting will be open to the public.

Dated: May 15, 1980.

James E. O'Neill,

Acting Archivist of the United States.

[FR Doc. 80-15985 Filed 5-23-80; 8:45 am]

BILLING CODE 6820-26-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Advisory Committees; Meetings

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. Appendix I), announcement is made of the following National advisory bodies scheduled to assemble during the month of June 1980.

Minority Advisory Committee, ADAMHA

June 18-20; 9:00 a.m.—Open Meeting, room 17-08B, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Marta Sotomayor, Ph.D., Room 13C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-3838.

Purpose: The Minority Advisory Committee, ADAMHA, advises the Secretary, Department of Health and Human Services, and the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, on needs, programs, and activities regarding minority alcohol, drug abuse, and mental health matters, and makes recommendations for possible solutions which meet the needs and concerns of minority groups throughout the United States. The Committee functions on an advisory capacity to the Administrator, ADAMHA, on those matters which relate to the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health.

Agenda: On June 18, agenda items include discussion of administrative matters, Committee reports, and special reports from Committee members. Other agenda items include status reports on: Responses to Recommendations of the First and Second National Conferences on Minority Group Alcohol, Drug Abuse, and Mental Health Issues and Phase II of the Racial Minority Manpower Development and Training Report, Hispanic Initiatives, Indochinese and Asian/Pacific Initiatives, and the Black College Initiatives. The remainder of the meeting will include meetings with the Administrator and Institute Directors and informational items.

Agenda items are subject to change as priorities dictate.

Rape Prevention and Control Advisory Committee

June 19–20; 9:00 a.m—Open meeting, Conference Room K, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Mary Lystad, Ph.D., Room 11A–44, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1910.

Purpose: the Rape Prevention and Control Advisory Committee advises the Secretary, Department of Health and Human Services, the Administrator, Alcohol, Drug Abuses, and Mental Health Administration, and the Director, National Institute of Mental Health, through the National Center for the Prevention and Control of Rape, on matters regarding the needs and concerns associated with rape in the United States and makes recommendations pertaining to activities to be undertaken by the Department to address the problems of rape.

Agenda: The entire meeting will be open to the public. The two day meeting of the Advisory Committee will be devoted to information gathering on incidence, including presentations by several Agencies around their statistics and activities in this area. Attendance by the public will be limited to space available.

Substantive information may be obtained from the contact persons listed above. Summaries of the meeting and rosters of committee members for the Minority Advisory Committee, ADAMHA will be furnished by Mr. James C. Helsing, Deputy Director, Office of Public Affairs, Room 6C–15, Parklawn Building, 5600 Fishers Lane, Rockvill, Maryland 20857, telephone: (301) 443–3783. For the rape Prevention and Control Advisory Committee meeting, summaries and rosters will be furnished by the Committee Management Officer, Office of the Associate Director for Extramural Programs, Room 9–95, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–4333.

Dated: May 20, 1980.

Elizabeth A. Connolly,

Committee Managment Officer, Alcohol, Drug, Abuse, and Mental Health Administration.

[FR Doc. 80-15936 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-88-M

Federal Council on the Aging; Meeting

The Federal Council on the Aging was established by the 1973 Amendments to the Older Americans Act of 1965 (Pub. L. 93–29, 42 U.S.C. 3015) for the purpose of advising the President, the Secretary of Health and Human Services, the Commissioner on Aging and the Congress on matters relating to the special needs of older Americans.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 1, Sec. 10, 1976) that the Council will hold a meeting June 16–17, 1980 from 9:30 a.m. to 5:00 p.m. and from 9:00 a.m. to 12:30 p.m. respectively in Rooms 425A–403A, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201.

The main focus of the agenda will be the discussion on the relationship between the Council's Congressionally mandated study and the Older Americans Act as originally conceived and presently structured. Strategies for soliciting public input as part of the Council's final report to Congress will be discussed at length.

Highlights of the agenda will be the presentation of the final report on the Older Workers Study and continuation of Council deliberation on issues relating to social security.

Other issues pertinent to the needs and concerns of the aged will also be discussed.

Further information on the Council may be obtained from the Federal Council on the Aging, Washington, D.C. 20201, telephone (202) 245–0441. FCA meetings are open for public observation.

Dated: May 19, 1980.

Nelson H. Cruikshank,

Chairman, Federal Council on the Aging.

[FR Doc. 80-15948 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-92-M

Long Term Care Committee; Meeting

The Federal Council on the Aging was established by the 1973 amendments to the Older Americans Act of 1965 (Pub. L. 93–29, 42 U.S.C. 3015) for the purpose of advising the President, the Secretary of Health and Human Services, the Commission on Aging, and the Congress, on matters relating to the special needs of older Americans.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. app. 1, sec. 10, 1976) that the Committee will hold a meeting on Tuesday, June 24, 1980 at 9:30 a.m. to 12:30 p.m. in Room 337–339A, Hubert Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201.

The agenda will consist of a discussion with Federal officials on two aspects of the committee's 1980 workplan: demographic assumptions for projections of need and costs.

Further information on the Council may be obtained from the Federal Council on the Aging, Washington, D.C. 20201, telephone (202) 245–0441. FCA meetings are open for public observation.

Dated: May 20, 1980.

Nelson H. Cruikshank,

Chairman, Federal Council on the Aging.

[FR Doc. 80-15949 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-92-M

Food and Drug Administration

[Docket No. 80P-0076]

Cerberonics, Inc.; Approval of Variance for Small Arms Laser Training and Evaluation Device

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces that a variance from the performance standard for laser products has been approved by the Bureau of Radiological Health for the Small Arms Laser Training and Evaluation Device. The product is a laser modification for small arms, primarily handguns, that is used to simulate firing practice for training purposes by projecting an invisible infrared (aproximately 900 nanometers in wavelength) beam of laser radiation onto a detection target.

DATES: The variance became effective May 2, 1980, and ends May 2, 1985.

ADDRESS: The application and all correspondence on the application have been placed on public display in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn E. Conklin, Bureau of Radiological Health (HFX–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3426.

SUPPLEMENTARY INFORMATION: Under the provisions of § 1010.4 (21 CFR 1010.4), Cerberonics, Inc., 5600 Columbia Pike, Falls Church, VA 22041, has been granted a variance from § 1040.10(h)(1)(iv) (21 CFR 1040(h)(1)(iv)) of the performance standard for laser products. The variance permits the manufacturer to introduce into commerce the laser product known as the Small Arms Laser Training and Evaluation Device without the required listing of all controls, adjustments and procedures for operation and maintenance, and without a warning statement provided with the product as user information. Suitable means of radiation protection will be provided by constraints on the physical and optical design. The product is a Class I laser

product and there are no controls, adjustments and procedures for operation and maintenance that will result in accessible laser radiation above the limits of Class I. The product shall bear the Variance Number 80P-0076.

By letter of May 2, 1980, the Director of the Bureau of Radiological Health approved the requested variance which terminates on May 2, 1985.

In accordance with § 1010.4 (21 CFR 1010.4), the application and all correspondence (including the written notice of approval) on this application have been placed on public display in the office of the Hearing Clerk, Food and Drug Administration, and may be seen from 9 a.m. to 4 p.m., Monday through Friday.

Dated: May 20, 1980

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-15947 Filed 5-23-80; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Environmental Quality

[Docket No. NI-17]

Intended Environmental Impact Statements

The Department of Housing and Urban Development gives notice that an Environmental Impact Statement (EIS) is intended to be prepared for each of the following projects under HUD programs as described in the appendices of the Notice: Rio Rancho Estates Subdivision, Sandoval County, New Mexico; and Rosemeade Subdivision, Carrollton, Denton County, Texas. This Notice is required by the Council on Environmental Quality under its rules (40 CFR Part 1500).

Interested individuals, governmental agencies, and private organizations are invited to submit information and comments concerning a particular project to the specific person or address indicated in the appropriate part of the appendices.

Particularly solicited is information on reports or other environmental studies planned or completed in the project area, issues and data which the EIS should consider, recommended mitigating measures and alternatives, and major issues associated with the proposed project. Federal agencies having jurisdiction by law, special expertise or other special interests should report their interests and indicate their readiness to aid the EIS effort as a "cooperating agency."

Issued at Washington, D.C., May 19, 1980.

Francis G. Haas,

Deputy Director, Office of Environmental Quality.

Appendix—EIS on Rio Rancho Estates, Sandoval County, N. Mex.

The Dallas Area Office of the Department of Housing and Urban Development intends to prepare an Environmental Impact Statement for a proposed subdivision to be known as Rio Rancho Estates located in Sandoval County, New Mexico. The purpose of this Notice is to solicit comments and recommendations from all interested persons and local, state and Federal agencies regarding the issues to be addressed in depth in the Environmental Impact Statement.

Description. The Real Estate Company of America, The Presley Company of New Mexico and the AMREP Corporation have individually filed applications with the Albuquerque Service Office for the Department to accept the three subdivisions for mortgage insurance under Section 203(b) of Title II of the National Housing Act of 1934. The AMREP Corporation has control of 3,152 additional acres of land yet to be developed. Sandoval County has planning and platting jurisdiction over the entire acreage. The Village of Corrales shares jurisdiction with the county for the areas which are situated within three miles of its incorporated boundaries. The total proposed development has approximately 5,000 single family residential units, 672 multifamily units and 74 acres of commercial property. When fully developed the area will provide housing for an estimated population of 16,185 persons. Each of the three developers has requested early start approval of 54 lots, 117 lots and 199 lots of their respective subdivisions.

Need. The Dallas Area has determined that three requests are related geographically and parts of a composite action, and may be best evaluated with a single Environmental Impact Statement.

Alternatives. The alternatives available to the Department are (1) accept the project as submitted, (2) accept the project with modifications, or (3) reject the project.

Scoping. No formal scoping meeting is anticipated for this project. It is the intent of this Notice to be considered a part of the process used for scoping the environmental impact statement. Any responses to this Notice will be used to help (1) determine significant environmental issues, and (2) identify data which the EIS should address.

Contact. Comments should be sent on or before June 13, 1980, to I. J. Ramsbottom, Environmental Officer, Dallas Area Office, Department of Housing and Urban Development, 2001 Bryan Tower, Dallas, Texas 75201. The commercial telephone number of this office is 214-767-8347 and the FTS number is 729-8347.

Appendix—EIS on Rosemeade Subdivision, Carrollton, Denton County, Tex.

The Dallas Area Office of the Department of Housing and Urban Development intends to prepare an Environmental Impact Statement for a proposed subdivision to be known as Rosemeade, located in that portion of the City of Carrollton which is in Denton County, Texas. The purpose of this Notice is to solicit comments and recommendations from all interested persons and local, state and Federal agencies regarding the issues to be addressed in depth in the Environmental Impact Statement.

Description. The Tex-Can Development Venture No. One, 830 Republic Bank Building, Dallas, Texas, proposes to develop a tract comprised of approximately 900 acres with 520 acres devoted to single family residential use. The Rosemeade subdivision will have Frankford Road as the south boundary, Standridge Drive and Josey Lane as its east boundary, Hebron Parkway as the north boundary and Old Denton Road and Indian Creek as the west boundary. When fully developed, the subdivision will have approximately 2221 residences which will accommodate a population of approximately 8,450 persons.

The developer has requested that the Department accept the subdivision for mortgage insurance under Section 203(b) of Title II of the National Housing Act of 1934. The developer has requested an early-start on 199 lots of the proposed subdivision.

Need. Due to the size and scope of the total proposed project the Dallas Area Office has determined that an Environmental Impact Statement will be prepared pursuant to Public Law 91-190, the National Environmental Policy Act of 1969.

Alternatives. The alternatives available to the Department are (1) accept the project as submitted, (2) accept the project with modifications, or (3) reject the project.

Scoping. No formal scoping meeting is anticipated for this project. It is the intent of this Notice to be considered a part of the process used for scoping the environmental impact statement. Any

responses to this Notice will be used to help (1) determine significant environmental issues, and (2) identify data which the EIS should address.

Contact. Comments should be sent on or before June 13, 1980, to I. J. Ramsbottom, Environmental Officer, Dallas Area Office, Department of Housing and Urban Development, 2001 Bryan Tower, Dallas, Texas 75201. The commercial telephone number of this office is 214–767–8347 and the FTS number is 729–8347.

[FR Doc. 80-15980 Filed 5-23-80; 8:45 am]

BILLING CODE 4210-01-M

Office of the Secretary

[Docket No. N-80-1004]

Privacy Act of 1974; Proposed Amendment to System of Records

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of proposed amendment to existing system of records.

SUMMARY: The Department is giving notice that it intends to amend the system location of the Section 8 Program Research Data Files (HUD/PD&R–7) system of records.

EFFECTIVE DATE: The amendment shall become effective on June 26, 1980, unless comments are received on or before that date which will result in a contrary determination.

ADDRESS: Rules Docket Clerk, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Robert English, Departmental Privacy Act Officer, Telephone 202–557–0605.

SUPPLEMENTARY INFORMATION: The Section 8 Program Research Data Files (HUD/PD&R–7) system of records supports a two phased effort to evaluate the Section 8 Program and the housing improvements experienced by participants in that program. The first phase emphasized urban participants. The second phase will emphasize rural participants and will be conducted by a HUD contractor located in Boone, North Carolina. For this reason the system location is being amended by adding Boone, North Carolina as an additional system location. The Section 8 Program Research Data Files System (HUD/PD&R–7) was published at 44 FR 72306 (December 13, 1979).

The System Location section is being amended to read as follows:

HUD/PD&R–7

SYSTEM NAME:

Section 8 Program Research Data Files.

SYSTEM LOCATION:

Cambridge, Massachusetts; Boone, North Carolina.

* * * * *

Authority: 5 U.S.C. 552(a), 88 Stat. 1896; Sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)).

Issued at Washington, D.C., May 19, 1980.

William A. Medina,

Assistant Secretary for Administration.

[FR Doc. 80-16038 Filed 5-23-80; 8:45 am]

BILLING CODE 4210-01-M

[Docket No. N-80-1005]

Privacy Act of 1974; Proposed Amendment to System of Records

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of proposed amendment to existing system of records.

SUMMARY: The Department is giving notice that it intends to amend the routine use of a system of records.

EFFECTIVE DATE: The amendment shall become effective without further notice on June 26, 1980, unless comments are received on or before that date which would result in a contrary determination.

ADDRESS: Rules Docket Clerk, Room 5218, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Robert English, Departmental Privacy Act Officer, Telephone 202–557–0605.

SUPPLEMENTARY INFORMATION: The amendment is adding a routine use to the system titled Pay and Leave Records of Employees (HUD/DEPT–34.) The routine use is to enable the Department to use contractor support in scanning and keying time and attendance data, and in producing input media and error listings. Although there is some question as to the requirement that this use be published, the Department determined publication is desirable to conform to the intent of the Privacy Act. The words "time and attendance data—to contractor for scanning, keying, producing error lists, and producing input media" have been added to the routine uses section of the notice. This addition does not require the submission of a report on a new system since it is compatible with the purpose for which the system is maintained. Additionally, the system manager has been identified as the Director, Personnel Systems and Payroll Division, Office of Personnel. The notice is published below in its entirety, as amended. Previously, the system was published at 44 FR 72296 (December 13, 1979). The prefatory statement containing General Routine Uses applicable to all of the Department's systems of records was published at 44 FR 72288 (December 13, 1979) and amended at 45 FR 26825 (April 21, 1980). Appendix A, which lists the addresses of HUD's field offices was published at 44 FR 72307 (December 13, 1979), and supplemented at 45 FR 6479 (January 18, 1980).

HUD/DEPT–34

SYSTEM NAME:

Pay and Leave Records of Employees.

SYSTEM LOCATION:

All Department offices. For a complete listing of offices, with addresses, see Appendix A.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

HUD employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number and employee number, grade, step, and salary; organization, retirement or FICA data as applicable; Federal, state and local tax deductions; regular and optional Government life insurance deduction(s), health insurance deduction and plan or code; cash award data; jury duty data; military leave data; pay differentials; union dues deduction; allotments by type and amount; financial institution code and employee account number; leave status and data of all types (including annual, compensatory, jury duty, maternity, military, retirement disability, sick, transferred, and without pay); time and attendance records, including leave applications and reports, individual daily time reports, adjustments to time and attendance, overtime reports, supporting data, such as medical certificates, number of regular, overtime, holiday, Sunday and other hours worked; pay period number and ending dates; cost of living allowances; mailing address; co-owner and/or beneficiary of bonds, marital status and number of dependents; and "Notification of Personnel Actions."

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See Routine Uses paragraphs in prefatory statement. Other routine uses: Transmittal of data to U.S. Treasury to effect issuance of paycheck to employees and distribution of pay according to employee directions for savings bonds, allotments, financial institutions and other authorized purposes. Annual reporting of W–2 statements to Internal Revenue Service, Social Security Administration, the individual, and taxing authorities of States, the District of Columbia, territories, possessions, and local governments, except Social Security Numbers will be reported only to such authorities that have satisfied the requirements set forth in Section 7(a)(2)(B) of the Privacy Act of 1974. To the Office of Personnel Management concerning pay, benefits, retirement deductions, and other information necessary for the Office to carry on its Government-wide personnel functions; to GAO—for audit; to other Federal government agencies—to facilitate employee transfers; to State agencies—to verify workmen's compensation injury claims; time and attendance data—to contractor for scanning, keying, producing error lists, and producing input media.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Manual, machine-readable and magnetic media.

RETRIEVABILITY:

Name of employee; Social Security Number.

SAFEGUARDS:

Physical, technical, and administrative security is maintained with all storage equipment and/or rooms locked when not in use. Admittance, when open, is restricted to authorized personnel only. All payroll personnel and computer operators and programmers are instructed and cautioned on the confidentiality of the records. Manual files kept in lockable desks, file cabinets and safes.

RETENTION AND DISPOSAL:

Retained on site until after GAO audit, then disposed of, or transferred to Federal Records Storage Centers in accordance with fiscal records program approval by GAO, as appropriate, or General Record Schedules of GSA.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Personnel Systems and Payroll Division, Office of Personnel, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

NOTIFICATION PROCEDURE:

For information, assistance, or inquiry about existence of records, contact the Privacy Act Officer at the appropriate location, in accordance with procedures in 24 CFR Part 16. A list of all locations is given in Appendix A.

RECORD ACCESS PROCEDURES:

The Department's rules for providing access to records to the individual concerned appear in 24 CFR Part 16. If additional information or assistance is required, contact the Privacy Act Officer at the appropriate location. A list of all locations is given in Appendix A.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting the contents of records and appealing initial denials, by the individual concerned, appear in 24 CFR Part 16. If additional information or assistance is needed, it may be obtained by contacting: (i) in relation to contesting contents of records, the Privacy Act Officer at the appropriate location. A list of all locations is given in Appendix A, (ii) in relation to appeals of initial denials, the HUD Departmental Privacy Appeals Officer, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

RECORD SOURCE CATEGORIES:

Subject individuals, supervisors, timekeepers, official personnel records, previous employers, or other Federal government agencies.

Authority: 5 U.S.C. 552a, 88 Stat. 1896; Sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)).

Issued at Washington, D.C., May 15, 1980.

William A. Medina,

Assistant Secretary for Administration.

[FR Doc. 80-16035 Filed 5-23-80; 8:45 am]

BILLING CODE 4210-01-M

[Docket No. N-80-1006]

Privacy Act of 1974; New System of Records

AGENCY: Department of Housing and Urban Development.

ACTION: Notification of new system of records.

SUMMARY: The Department is giving notice of a new system of records it intends to maintain which is subject to the Privacy Act of 1974.

EFFECTIVE DATE: The system shall become effective without further notice on June 26, 1980, unless comments are received on or before that date which would result in a contrary determination.

ADDRESS: Rules Docket Clerk, Room 5218, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Robert English, Departmental Privacy Act Officer, Telephone 202–557–0605.

SUPPLEMENTARY INFORMATION: The system is Congregate Housing Services Program Data Files which will contain information about Congregate Housing Services Program (CHSP) applicants residing in Public Housing and Section 202 (Elderly or Handicapped) projects. The purpose for collecting the information is to: (1) describe the characteristics of groups of participants in annual reports to Congress; (2) compare participant socio-economic and physical functioning profile with characteristics of tenants in other Public Housing and Section 202 projects for use in the program evaluation; and (3) track participants over time to measure effect of CHSP on institutionalization. All of the information reported will be representative and will not identify specific individuals. A new system report was filed with the Speaker of the House, the President of the Senate, and the Office of Management and Budget on April 1, 1980. Appendix A, which lists the addresses of HUD's field offices was published at 44 FR 72307 (December 13, 1979) and supplemented at 45 FR 6479 (January 28, 1980).

HUD/DEPT–64

SYSTEM NAME:

Congregate Housing Services Program Data Files.

SYSTEM LOCATION:

Headquarters.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Congregate Housing Services Program (CHSP) applicants residing in grantee Public Housing and Sec. 202 (Elderly or Handicapped) projects.

CATEGORIES OF RECORDS IN THE SYSTEM:

The files will contain the following data on program applicants: name, CHSP code (file) number, race, sex, date of birth, living arrangement, marital status, number of minors, yearly gross income, contract rent, total housing expense, size of unit, sources of income,

handicap type, disability type, date of admission to project, yearly gross income at admission, income sources at admission, current and previous services received by program type, dates of service received, date of admission to CHSP, type and quantity (e.g. hours per week) of services received in CHSP, date left CHSP, status at termination, post-program status, score on Activities of Daily Living (ADL) tests.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Congregate Housing Services Act of 1978, 42 U.S.C. 8001.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Routine uses: HUD contractor—for CHSP program evaluation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

In file folders and on magnetic tape/disc/drum.

RETRIEVABILITY:

Name, CHSP code (file) number, race, sex, date of birth, living arrangement, marital status, number of minors, yearly gross income, contract rent, total housing expense, size of unit, sources of income, handicap type, disability type, date of admission to project, yearly gross income at admission, income sources at admission, current and previous services received by program type, dates of service received, date of admission to CHSP, type of services received in CHSP, date left CHSP, status at termination, post-program status, score on Activities of Daily Living (ADL) tests.

SAFEGUARDS:

Manual files will be kept in lockable cabinets in a secured area; computer records will be maintained in a separate secured area. Access to either type of record will be limited to authorized personnel

RETENTION AND DISPOSAL:

System will be retained through completion of evaluations or duration of the program whichever is longer.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Consumer Affairs, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410.

NOTIFICATION PROCEDURE:

For information, assistance, or inquiry about existence of records, contact the Privacy Act Officer at the Headquarters location, in accordance with 24 CFR Part 16. This location is given in Appendix A.

RECORD ACCESS PROCEDURES:

The Department's rules for providing access to records to the individual concerned appear in 24 CFR Part 16. If additional information or assistance is required, contact the Privacy Act Officer at Headquarters. This location is given in Appendix A.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting the contents of records and appealing initial denials, by the individual concerned, appear in 24 CFR Part 16. If additional information or assistance is needed, it may be obtained by contacting: (i) in relation to contesting contents of records, the Privacy Act Officer at the Headquarters location. This location is given in Appendix A; (ii) in relation to appeals of initial denials, the HUD Departmental Privacy Appeals Officer, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410.

RECORD SOURCE CATEGORIES:

Subject individuals, Professional Assessment Committee, Project Managers.

Authority: 5 U.S.C. 552a, 88 Stat. 1896; Sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)).

Issued at Washington, D.C., May 20, 1980.

William A. Medina,

Assistant Secretary for Administration.

[FR Doc. 80-16034 Filed 5-23-80; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA-8102-26 and AA-8102-28]

Alaska Native Claims Selections

Correction

In FR Doc. 80-14254, appearing at page 30544, in the issue of Thursday, May 8, 1980, please make the following corrections:

1. On page 30545, in the second column, under the paragraph numbered 2., in the fifth line, the date "July 7, 1978" should be corrected to read "July 7, 1958".

2. On the same page, in the third column, the second full paragraph, in the fourth line, the date "April 26," should be corrected to read "April 23,".

BILLING CODE 1505-01-M

[AA-6645-B]

Alaska Native Claims Selection

Correction

In FR Doc. 80-4256, appearing at page 30543, in the issue of Thursday, May 8, 1980, please make the following correction:

On page 30543, in the third column, in the seventh paragraph under the line "Seward Meridian Alaska (Unsurveyed)" the following line should appear: "T 37 S., R 49 W".

BILLING CODE 1505-01-M

[F-14913-A and F-14913-B]

Alaska Native Claims Selection

On September 5, 1974, Nik'aghun, Limited, for the Native village of Nulato, filed selection application F-14913-A and on December 3, 1974, filed selection application F-14913-B under the provisions of Sec. 12 of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 701; 43 U.S.C. 1601, 1611 (1976)) (ANCSA), for the surface estate of certain lands in the vicinity of Nulato.

The applications excluded several water bodies as being navigable. Because these water bodies have been determined to be nonavigable, they are considered to be public lands withdrawn under Sec. 11(a)(1) and available for selection by the village pursuant to Sec. 12(a) of the Alaska Native Claims Settlement Act.

Section 12(a) and 43 CFR 2651.4(b) and (c) provide that the village corporation shall select all available lands within the township or townships within which the village is located, and that additional lands selected shall be compact and in whole sections. The regulations also provide that the area selected will not be considered to be reasonably compact if it excludes other lands available for selection within its exterior boundaries.

For these reasons, the water bodies which were improperly excluded in the applications of Nik'aghun, Limited are considered selected.

On April 6, 1978, in accordance with Title 10, Chapter 05, Secs. 396 and 399 of the Alaska Business Corporation Act, and as authorized by Public Law 94-204, Sec. 30 (89 Stat. 1148), the Native villages of Galena (Notaaghleedin, Limited), Kaltag (Takathlee-tondin, Incorporated), Nulato (Nik'aghun, Limited) and Koyukuk (Mineelghaadza', Limited) formed a new corporation which consolidated individual village

interests into one single consituent corporation, Gana-a'Yoo, Limited.

As to lands described below, the applications, as amended, are properly filed and meet the requirements of the Alaska Native Claims Settlement Act and of the regulations issued pursuant thereto. These lands do not include any lawful entry perfected under or being maintained in compliance with laws leading to acquisition of title.

In view of the foregoing, the surface estate of the following described lands, selected pursuant to Sec. 12(a) of ANCSA, aggregating approximately 106,471 acres, is considered proper for acquisition by Gana-a'Yoo, Limited and is approved for conveyance pursuant to Sec. 14(a) of ANCSA:

Kateel River Meridian, Alaska (Unsurveyed)

T. 7 S., R. 2 E.
Secs. 22 to 27, inclusive, all;
Secs. 34, 35 and 36, all.
Containing approximately 5,760 acres.

T. 8 S., R. 2 E.
Secs. 1 and 2, all;
Secs. 11 to 14, inclusive, all.
Containing approximately 3,840 acres.

T. 9 S., R. 2 E.
Sec. 1, all;
Secs. 12 to 15, inclusive, all;
Secs. 20 to 24, inclusive, all;
Secs. 27 to 32, inclusive, all.
Containing approximately 10,164 acres.

T. 10 S., R. 2 E.
Secs. 10 to 34, inclusive, all;
Sec. 35, excluding Native allotment F-03508;
Sec. 36, all.
Containing approximately 17,141 acres.

T. 7 S., R. 3 E.
Secs. 19 to 31, inclusive, all;
Sec. 32, excluding Native allotment F-15474 Parcel C;
Secs. 33 and 34, excluding Native allotment F-13465;
Secs. 35 and 36, all.
Containing approximately 11,300 acres.

T. 8 S., R. 3 E.
Secs. 1 to 4, inclusive, all;
Sec. 5, excluding Native allotments F-15474 Parcel C and F-18916 Parcel B;
Secs. 6 to 12, inclusive, all;
Sec. 13, excluding Native allotment F-17642;
Sec. 14, excluding Native allotments F-17164, F-13456 and F-17642;
Sec. 15, excluding Native allotment F-13456;
Sec. 22, all;
Sec. 23, excluding Native allotments F-13456, F-13468 and F-17164;
Sec. 24, all;
Sec. 25, excluding Native allotment F-13468;
Sec. 26, excluding Native allotments F-13468 and F-13529;
Secs. 27 and 34, all;
Sec. 35, excluding Native allotments F-13529, F-15550 and F-17110;
Sec. 36, all.
Containing approximately 14,215 acres.

T. 9 S., R. 3 E.
Sec. 1, excluding Native allotment F-15542;
Sec. 2, excluding Native allotments F-13466 and F-15550;
Sec. 3, excluding Native allotment F-19459;
Sec. 4, excluding Native allotments F-15558, F-16628 and F-19459;
Sec. 5, excluding Native allotment F-16628;
Secs. 6, 7 and 8, all;
Sec. 9, excluding Native allotments F-15548 Parcel A, F-15558, F-17173 and F-19459;
Sec. 10, excluding Native allotments F-15547, F-15548 Parcel A and F-19459;
Sec. 11, excluding Native allotments F-13464, F-14032 and F-15551;
Sec. 12, excluding Native allotments F-13457, F-13563, F-15494, F-15533, F-15542 and F-15551;
Sec. 13, excluding Native allotments F-13563, F-13564, F-15533, and F-15552;
Sec. 14, excluding Native allotment F-13564;
Sec. 15, all;
Sec. 16, excluding Native allotment F-15548 Parcel B;
Sec. 17 to 23, inclusive, all;
Sec. 24, excluding Native allotments F-032036, F-15535 and F-15552 and the Yukon River;
Sec. 26 and 27, excluding Native allotment F-13458 Parcel B and the Yukon River;
Sec. 28, 29 and 30, all;
Sec. 33, excluding Native allotment F-13525;
Sec. 34, excluding Native allotment F-13458 Parcel B and the Yukon River.
Containing approximately 15,744 acres.

T. 10 S., R. 3 E.

Sec. 4, excluding Native allotments F-13525, F-13426 and F-13534 and the Yukon River;
Sec. 17, excluding Native allotments F-13527, and F-13545 and the Yukon River;
Sec. 18, excluding Native allotment F-13545;
Sec. 19, excluding Native allotment F-13530;
Containing approximately 1,615 acres.

T. 8 S., R. 4 E.

Sec. 4 to 9, inclusive, all;
Sec. 16 to 21, inclusive, all;
Sec. 28 to 29, all;
Sec. 30, excluding Native allotments F-13455 and F-13460;
Sec. 31, excluding Native allotment F-13460;
Sec. 32 and 33, all.
Containing approximately 11,164 acres.

T. 9 S., R. 4 E.

Sec. 1, excluding Patsy Slough;
Sec. 2, excluding Native allotments F-13567 and F-15544, the Yukon River and Patsy Slough;
Sec. 3, excluding Native allotment F-13580 and the Yukon River;
Sec. 4, excluding U.S. Survey 4370, Native allotments F-14029 and F-14034 and the Yukon River;
Sec. 5, excluding U.S. Survey 4370;
Sec. 6, all;
Sec. 7, excluding Native allotments F-13576 F-15494 and F-15533;
Sec. 8, excluding U.S. Survey 724, U.S. Survey 4370, Native allotments F-027525 and Mukluk Slough;
Sec. 9, excluding U.S. Survey 4370, Native allotments F-14029, F-14034, F-16432 and F-027525, the Yukon River and Mukluk Slough;
Sec. 10, excluding the Yukon River;
Sec. 11, excluding Native allotments F-15544 and the Yukon River;
Sec. 12, 13 and 14, all;
Sec. 15, excluding Native allotments F-13581 and F-14044 and the Yukon River;
Sec. 16, excluding Native allotments F-13581, the Yukon River and Mukluk Slough;
Sec. 17, excluding U.S. Survey 724, the Yukon River and Mukluk Slough;
Sec. 18, excluding Native allotments F-13425 Parcel B, F-13576, F-15533 and F-15552 and the Yukon River;
Sec. 19, excluding Native allotments F-032036 and F-15552 and the Yukon River;
Sec. 20, excluding the Yukon River and Mukluk Slough;
Sec. 21, excluding Native allotment F-15511 and the Yukon River;
Sec. 22, excluding Native allotment F-13581;
Secs. 23 to 28, inclusive, all;
Secs. 29, 30 and 31, excluding the Yukon River;
Secs. 32 to 36, inclusive, all.
Containing approximately 15,528 acres.
Aggregating approximately 106,471 acres

The conveyance issued for the surface estate of the lands described above shall contain the following reservations to the United States:

1. The subsurface estate therein, and all rights, privileges, immunities, and appurtenances, of whatsoever nature, accruing unto said estate pursuant to the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 704; 43 U.S.C. 1601, 1613(f));

2. Pursuant to Sec. 17(b) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 708; 43 U.S.C. 1601, 1616(b)), the following public easements, referenced by easement identification number (EIN) on the easement maps attached to this document, copies of which will be found in case file F-14913-EE, are reserved to the United States. All easements are subject to applicable Federal, State, or Municipal corporation regulation. The following is a listing of uses allowed for each type of easement. Any uses which are not specifically listed are prohibited.

25 Foot Trail—The uses allowed on a twenty-five (25) foot wide trail easement are: travel by foot, dogsled, animals, snowmobiles, two and three-wheel vehicles, and small all-terrain vehicles (less than 3,000 lbs. Gross Vehicle Weight (GVW)).

50 Foot Trail—The uses allowed on a fifty (50) foot wide trail easement are: travel by foot, dogsled, animals, snowmobiles, two and three-wheel vehicles, small and large all-terrain vehicles, track vehicles, and four-wheel drive vehicles.

One Acre Site—The uses allowed for a site easement are: vehicle parking (e.g., aircraft, boats, ATV's, snowmobiles, cars, trucks), temporary camping, and loading or unloading. Temporary camping, loading, or unloading shall be limited to 24 hours.

a. (EIN 6 C5) An easement for a proposed access trail, twenty-five (25)

feet in width, from the left bank of the Yukon River in Sec. 21, T. 10 S., R. 3 E., Kateel River Meridian, southeasterly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement.

b. (EIN 9 C3, C5) An easement for a proposed access trail, twenty-five (25) feet in width, from the right bank of the Yukon River in Sec. 4, T. 10 S., R. 3 E., Kateel River Meridian, westerly to public lands in Sec. 36, T. 9 S., R. 2 E., Kateel River Meridian. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement.

c. (EIN 14 C6) A one (1) acre site easement, upland of the ordinary high-water mark, in Sec. 20, T. 9 S., R. 4 E., Kateel River Meridian, on Nulato Island in the Yukon River. The uses allowed are those listed above for a one (1) acre site easement.

d. (EIN 15 C3, C5) An easement for a proposed access trail, fifty (50) feet in width, from Tract C of U.S. Survey 4370 in Sec. 5, T. 9 S., R. 4 E., Kateel River Meridian, westerly to public lands in T. 8 S., R. 1 E., Kateel River Meridian. The uses allowed are those listed above for a fifty (50) foot wide trail easement.

The grant of the above-described lands shall be subject to:

1. Issuance of a patent confirming the boundary description of the unsurveyed lands hereinabove granted after approval and filing by the Bureau of Land Management of the official plat of survey covering such lands;

2. Valid existing rights therein, if any, including but not limited to those created by any lease (including a lease issued under Sec. 6(g) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 341; 48 U.S.C. Ch. 2, Sec. 6(g))), contract, permit, right-of-way, or easement, and the right of the lessee, contractee, permittee, or grantee to the complete enjoyment of all rights, privileges, and benefits thereby granted to him. Further, pursuant to Sec. 17(b)(2) of the Alaska Native Claims Settlement Act of December 18, 1971 (43 U.S.C. 1601, 1616(b)(2))(ANCSA), any valid existing right recognized by ANCSA shall continue to have whatever right of access as is now provided for under existing law;

3. Requirements of Sec. 14(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 703; 43 U.S.C. 1601, 1613(c)), that the grantee hereunder convey those portions, if any, of the lands hereinabove granted, as are prescribed in said section; and

4. A right-of-way, F-18826, traversing protracted N½ Sec. 9, T. 9 S., R. 4 E., Kateel River Meridian, for a Federal Aid Highway, Act of August 27, 1958 (72 Stat. 885; 23 U.S.C. 317).

Gana-a'Yoo, Limited, for the village of Nulato, is entitled to conveyance of 115,200 acres of land selected pursuant to Sec. 12(a)(1) of ANSCA. Together with the lands herein approved, the total acreage conveyed or approved for conveyance is approximately 106,471 acres. The remaining entitlement of approximately 8,729 acres will be conveyed at a later date.

Pursuant to Sec. 14(f) of ANSCA, conveyance of the subsurface estate of the lands described above shall be issued to Doyon, Limited when the surface estate is conveyed to Gana-a'Yoo, Limited and shall be subject to the same conditions as the surface conveyance.

Within the above described lands, only the following inland water bodies are considered to be navigable:

The Yukon River and its interconnecting sloughs.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice of this decision is being published once in the **Federal Register** and once a week, for four (4) consecutive weeks, in the Fairbanks Daily News-Miner. Any party claiming a property interest in lands affected by this decision may appeal the decision to the Alaska Native Claims Appeal Board, P.O. Box 2433, Anchorage, Alaska 99510 with a copy served upon both the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513 and the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage, Alaska 99501, also:

1. Any party receiving service of this decision shall have 30 days from the receipt of this decision to file an appeal.

2. Any unknown parties, any parties unable to be located after reasonable efforts have need expended to locate, and any parties who failed or refused to sign the return receipt shall have until June 25, 1980, to file an appeal.

3. Any party known or unknown who may claim a property interest which is adversely affected by this decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Alaska Native Claims Appeal Board.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeals. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, 701 C street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the parties to be served with a copy of the notice of appeal are:

Gana-a'Yoo, Limited, Box 38, Galena, Alaska 99741.

Doyon, Limited, First and Hall Streets, Fairbanks, Alaska 99701.

Ricky M. Elliott,

Chief, Branch of Adjudication.

[FR Doc. 80-15984 Filed 5-23-80; 8:45 am]

BILLING CODE 4310-84-M

[U-45897]

Utah; Proposed Withdrawal and Reservation of Lands

Correction

In FR Doc. 80-13780, appearing on page 29644, in the issue of Monday, May 5, 1980 make the following corrections.

On page 29644, second column, the tenth line from the bottom reading: "SW¼SE¼SW¼;" should have read: "SW¼, SE¼SW¼;".

In the third column, the fifth and sixth lines should have been set forth on three lines as follows:
"Secs. 30 and 31."
"T. 13 S., R. 18 W., "
"Sec. 6."

BILLING CODE 1505-5-M

Heritage Conservation and Recreation Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before May 16, 1980. Pursuant to section 1202.13 of 36 CFR Part 1202, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by June 11, 1980.

Carol Shull,

Acting Keeper of the National Register.

ARIZONA

Maricopa County

Gilbert, *Gilbert Elementary School,* Elliot and Gilbert Rds.

Tempe, *Long, Samuel C., House,* 27 E. 6th St.

CALIFORNIA

Los Angeles County

Pasadena, Bolton, Dr. W. T., House, 370 W. Del Mar Blvd.

Marin County

Sausalito, *Barrett, William G., House (Casa Madrona Hotel)* 156 Bulkley Ave.

Monterey County

Salinas, *Bontadelli, Peter J., House,* 119 Cayuga St.

Sacramento County

Walnut Grove, *Walnut Grove Gakuen Hall,* Pine and C Sts.

San Bernardino County

Silver Lake vicinity, *Archeological Site CA-SBR-3186*

San Joaquin County

Lodi, *Lodi Arch,* Pine St.

Santa Cruz County

Watsonville, *Judge Lee House,* 128 E. Beach St.

Sonoma County

Sebastopol, *Strout, George A., House, 253 Florence Ave.*

GEORGIA

Cobb County

Smyrna vicinity, *Carmichael, J. H., Farm, and General Store,* SE of Smyrna at 501 Log Cabin Rd.

Fulton County

Atlanta, *Underground Atlanta Historic District,* Roughly bounded by Martin Luther King, Jr., Dr., Central Ave., Wall and Peachtree Sts.

Stewart County

Richland, *Smith-Alston House,* 405 Ponder St.

Sumter County

Americus vicinity, *Liberty Hall,* SE of Americus on S. Lee Street Rd.

KENTUCKY

Hopkins County

White Plains vicinity, *Archeological Site 15 Hk 46 and 47*

MAINE

Androscoggin County

Auburn, *Cushman, Charles L., House,* 8 Cushman Pl.
Poland, *Poland Railroad Station,* Harris Hill and Plains Rd.

Aroostook County

Houlton., *Market Square Historic District,* Market Sq., Main, Water and Court Sts.

Cumberland County

Portland, *Brown, Harrison B., House,* 400 Danforth St.
Portland, *Williston-West Church and Parish House,* 32 Thomas St.

Kennebec County

Augusta, *South Parish Congregational Church and Parish House,* Church St.

Oxford County

Buckfield, *Union Church,* Off ME 140

Somerset County

Fairfield, *Gerald, Amos, House,* 107 Main St.
Solon vicinity, *South Solon Meetinghouse,* 5 mi. SE of Solon

York County

Buxton, *First Congregational Church of Buxton,* ME 112
Limington, *Limington Academy,* ME 117
Sanford, *Emergy Homestead,* 1 and 3 Lebanon St.

MARYLAND

Montgomery County

Glen Echo, *Chautauqua Tower,* Glen Echo Park

MASSACHUSETTS

Middlesex County

Cambridge, *Colburn, Sarah Foster, House,* 7 Dana St.

Suffolk County

Boston, *All Saints' Church,* 211 Ashmont St.
Boston, *Charles Playhouse,* 74-78 Warrenton St.
Boston, *Stearns, R. H. B., Building,* 140 Tremont St.

Worchester County

Grafton, *Grafton Inn,* 25 Central Sq.

MINNESOTA

Cass County

Pine River vicinity, *Sherwood Forest Lodge Complex,* SE of Pine River on SR 77

Crow Wing County

Nisswa, *Minnewawa Lodge,* Off MN 13

MONTANA

Lake County

Polson, *Polson Feed Mill,* 501 Main St.

UTAH

Sevier County

Elsinore vicinity, *Elsinore Sugar Factory,* E of Elsinore

VERMONT

Orange County

Brookfield Center *Newton, Marvin, House,* Ridge Rd.

WEST VIRGINIA

Mason County

Leon vicinity, *McCausland, Gen. John, House,* S of Leon

[FR Doc. 80-15787 Filed 5-23-80; 8:45 am]
BILLING CODE 4310-03-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 241; Rule 19; Second Revised Exemption No. 149]

Detroit Terminal Railroad Co. and Detroit and Toledo Shore Line Railroad Co.; Exemption Under Mandatory Car Service Rules

Because of the inability of these railroads to furnish an adequate number of gondola cars, The Detroit Terminal Railroad Company and The Detroit and Toledo Shore Line Railroad Company are not supplying shippers gondola cars of suitable ownership to maintain operations, thereby threatening to close factories and create substantial economic loss.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19:

The Detroit Terminal Railroad Company and The Detroit and Toledo Shore Line Railroad Company are authorized to accept from shippers general service plain gondola cars bearing mechanical designations "GA," "GB," "GD," "GH," "GS," and "GT," as listed in the Official Railway Equipment Register, ICC-RER No. 6410-D issued by W. J. Trezise, or successive issues thereof, regardless of the provisions of Car Service Rule 2.

It is further ordered, That:

This exemption shall not apply to cars of Mexican or Canadian ownership or to cars subject to Interstate Commerce Commission or Association of American Railroads' Orders requiring return of cars to owners.

Effective May 31, 1980.

Expires August 31, 1980.

Issued at Washington, D.C., May 14, 1980.

Interstate Commerce Commission.

Joel E. Burns,

Agent.

[FR Doc. 80-15999 Filed 5-23-80; 8:45 am]
BILLING CODE 7035-01-M

[ICC Order No. 68-A Under Service Order No. 1344]

Illinois Central Gulf Railroad Co.; Rerouting Traffic

Upon further consideration of I.C.C. Order No. 68, and good cause appearing therefor:

It is ordered,

I.C.C. Order No. 68 is vacated.

This order shall become effective May 15, 1980, and shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. A copy shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., May 15, 1980.

Interstate Commerce Commission.

Joel E. Burns,

Agent.

[FR Doc. 80-15998 Filed 5-23-80; 8:45 am]
BILLING CODE 7035-01-M

[Volume No. 14]

Petitions, Applications, Finance Matters (Including Temporary Authorities), Alternate Route Deviations, Intrastate Applications, Gateways, and Pack and Crate.

Petitions for Modification, Interpretation or Reinstatement of Motor Carrier Operating Rights Authority

The following petitions seek modification or interpretation of existing motor carrier operating rights authority, or reinstatement of terminated motor carrier operating rights authority.

All pleadings and documents must clearly specify the suffix numbers (e.g., M1 F, M2 F) where the docket is so identified in this notice.

The following petitions, filed on or after March 1, 1979, are governed by Special Rule 247 of the Commission's General Rules of Practice (49 CFR 1100.247). These rules provide, among other things, that a *petition to intervene either with or without leave* must be filed with the Commission within 30 days after the date of publication in the Federal Register with a copy being furnished the applicant. Protests to these applications will be *rejected.*

A petition for intervention without leave must comply with Rule 247(k) which requires petitioner to demonstrate that if (1) holds operating authority permitting performance of any of the service which the applicant seeks authority to perform, (2) has the necessary equipment and facilities for performing that service, and (3) has performed service within the scope of the application either (a) for those supporting the application, or, (b) where the service is not limited to the facilities of particular shippers, from and to, or between, any of the involved points.

Persons unable to intervene under Rule 247(k) may file a petition for leave to intervene under Rule 247(l). In deciding whether to grant leave to intervene, the Commission considers, among other things, whether petitioner has (a) solicited the traffic or business of those persons supporting the application, or, (b) where the identity of those supporting the application is not included in the published application notice, has solicited traffic or business identical to any part of that sought by applicant within the affected marketplace. Another factor considered is the effects of any decision on petitioner's interests.

Samples of petitions and the text and explanation of the intervention rules can be found at 43 FR 50908, as modified at 43 FR 60277.

Petitions not in reasonable compliance with these rules may be rejected. Note that Rule 247(e), where not inconsistent with the intervention rules, still applies. Especially refer to Rule 247(e) for requirements as to supplying a copy of conflicting authority, serving the petition on applicant's representative, and oral hearing requests.

MC 84687 (Sub-2MIF), Notice of filing of Petition to Modify Commodity Description), filed April 3, 1980. Petitioner: VETERANS TRUCK LINE, INC., P.O. Box 218, Bristol, WI 53104. Representative: Steven L. Weiman, Suite 145, 4 Professional Dr., Gaithersburg, MD 20760. Petitioner holds motor common carrier authority in Certificate No. MC 84687 Sub 2, issued December 6, 1977, authorizing transportation, over irregular routes, of (1) *fresh and frozen meats, meat products, meat by-products, poultry and dairy products, frozen fish, fresh packed pickles and salad dressing,* from Chicago, IL, to points in Kenosha, Racine, Milwaukee, and Waukesha Counties, WI, and (2) *fresh and frozen meats, meat products and meat by-products,* from New Berling, Ft. Atkinson, and Milwaukee, WI, to Chicago, IL, RESTRICTION: The authority granted herein is restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. By the instant petition, partitioner seeks to modify the commodity description so as to read: "foodstuffs".

MC 87909 (Sub-24MIF), filed February 26, 1980. Notice of Petition to Delete a Restriction. Petitioner: Kroblin Transportation Systems, Inc., 4616 E. 67th Street, P.O. Box 21222, Tulsa, OK 74121. Representative: John P. Rhodes, P.O. Box 5000, Waterloo, IA 50704. Petitioner holds Motor Common Carrier Certificate MC 87909 (Sub 24) issued February 11, 1977 which authorizes transportation over regular routes of: *General commodities,* except money and jewelry, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment, Between Leon, Iowa, and St. Joseph, MO, serving the intermediate points of Bethany, MO, and those between Bethany, MO, and Leon, IA, and the off-route points of Ridgeway, MO, without restriction; and intermediate points between Bethany and St. Joseph, MO, restricted to Southbound traffic only: From Leon over U.S. Highway 69 to junction U.S. Highway 36, thence over U.S. Highway 36 to St. Joseph, and return over the same route. Between Leon, IA, and Des Moines, IA, serving all intermediate points, and the off-route points of Van Wert and Weldon, IA; also serving all intermediate and off-route points within 12 miles of the central post office at Des Moines (except Altoona, Ankeny, Carlisle, Des Moines, and Norwalk, IA): From Leon over U.S. Highway 69 to Des Moines, and return over the same route. *General commodities,* except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment, between Eagleville, MO, and Kansas City, KS, serving the intermediate points of Bethany, Pattonsburg, and Kansas City, MO, and the off-route points of Ridgeway, New Hampton, and Civil Bend, MO, without restriction; and intermediate and off-route points within 10 miles of Bethany (except Ridgeway, MO), restricted to pickup of livestock: From Eagleville over U.S. Highway 69 to Kansas City, KS, and return over the same route. Between Eagleville, MO, and St. Joseph, MO, serving the intermediate points of Bethany, Pattonsburg, and Winston, MO, and the off-route points of Ridgeway and New Hampton, MO: From Eagleville over U.S. Highway 69 to Cameron, MO, thence over U.S. Highway 36 to junction MO Highway 6, thence over MO Highway 6 to St. Joseph, and return over the same route. Restrictions: The above authority is restricted against (a) its use in connection with traffic originating at Kansas City and St. Joseph, MO, and points in their respective commercial zones and the intermediate and off-route points in MO on the regular routes described above and points in their respective commercial zones, and destined to points in that portion of IA lying on, east and south of a line beginning at the IA-MO State line and extending along U.S. Highway 169 to its junction with U.S. Highway 30 to Cedar Rapids, thence over U.S. Highway 151 to its junction with IA Highway 64, thence over IA Highway 64 to the IA-IL State line, including Cedar Rapids, IA and points in its commercial zone and points in IL within the Davenport, IA and Rock Island and Moline, IL, commercial zones as defined by the Commission, but not including Ames and Marshalltown, IA and points in their respective commercial zones; (b) its use in connection with traffic originating at points in that protion of IA described in (a) above, including Cedar Rapids and points in its commercial zone and points in IL within the Davenport, IA and Rock Island and Moline, IL, commercial zones as defined by the Commission, but not

including Ames and Marshalltown and points in their respective commercial zones and destined to Kansas City and St. Joseph, MO, and points in their respective commercial zones and the intermediate and off-route points in MO on the regular routes described above, and points in their respective commercial zones; (c) its use in connection with traffic originating at St. Joseph and Kansas City, MO, and points in their respective commercial zones and destined to Chicago, Aurora, Chicago Heights, Clearing, Hegewisch, Morris, Villa Park, and West Pullman, IL, and points in their respective commercial zones, and points in IL on the regular route authority of Takin Bros. Freight Line, Inc. between Chicago, IL and Mason City, IA beginning at Chicago and extending over IL Highway 38 to Dixon and thence over IL Highway 2 to its junction with U.S. Highway 30 (all formerly Alternate U.S. Highway 30), thence U.S. Highway 30 to Cedar Rapids, IA, and thence over described highways to Mason City; (d) its use in connection with traffic originating at Chicago, Aurora, Chicago Heights, Clearing, Hegewisch, Morris, Villa Park, and West Pullman, IL, and points in their respective commercial zones and points in IL on the described regular route authority of Takin Bros. Freight Line, Inc., and destined to Kansas City and St. Joseph, MO, and points in their respective commercial zones; and (e) the transportation of hides, skins, and chromes and pieces therefrom, from Kansas City and St. Joseph, MO, and points in their respective commercial zones. By instant Petitioner seeks to modify the authority as follows: Deletion of the entire restriction now attached to MC-87909 (Sub No. 24).

MC 109821 (M2F) and (Subs. 40, 53, and 66) (MIF), Notice of Filing of Petition to Modify Certificates, filed March 20, 1980. Petitioner: TAYNTON FREIGHT SYSTEM, INC., 40 Main St., Wellsboro, PA 16901. Representative: Michael R. Werner, P.O. Box 1409, 167 Fairfield Road, Fairfield, NJ 07006. Petitioner holds motor *common carrier* certificates in MC 109821 and Subs. 40, 53, and 66, issued June 7, 1977, September 23, 1976, December 11, 1976, and December 19, 1979, respectively. MC 109821 authorizes transportation, over regular routes and irregular routes, of (A) *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment),

Between Niagara Falls, NY, and Batavia, NY, serving all intermediate and off-route points in Niagara and Genesee Counties: From Niagara Falls over NY Hwy 31 to Lockport, NY, thence over NY Hwy 77 to junction NY Hwy 5, thence over NY Hwy 5 to Batavia, and return over the same route.

Between Warsaw, NY, and Niagara Falls, NY, serving all intermediate points and off-route points in Wyoming, Genesee, and Niagara Counties, NY: From Warsaw over US Hwy 20–A to junction NY Hwy 77, thence over NY Hwy 77 to junction NY Hwy 31 to Lockport, NY, thence over NY Hwy 31 to Niagara Falls, and return over the same route.

Between Warsaw, NY, and Rochester, NY, serving all intermediate points and off-route points in Monroe, Genesee, and Wyoming Counties, NY: From Warsaw over US Hwy 20–A to junction NY Hwy 98, thence over NY Hwy 98 to junction NY Hwy 33 at Batavia, thence over NY Hwy 33 to Rochester, and return over the same route.

Between Warsaw, NY and Batavia, NY, serving all intermediate and off-route points in Wyoming and Genesee Counties, NY: From Warsaw over US Hwy 20–A to junction NY Hwy 246 at Perry Center, NY, thence over NY Hwy 246 to junction NY Hwy 63, and thence over NY Hwy 63 to Batavia, and return over the same route.

Between Perry Center, NY, and Buffalo, NY, serving all intermediate and off-route points in Erie and Wyoming Counties, NY: From Perry Center over U.S. Hwy 20–A to junction NY Hwy 16, thence over NY Hwy 16 to Buffalo (also over U.S. Hwy 20–A to junction NY Hwy 400, thence over NY Hwy 400 to Buffalo), and return over the same route.

Between Batavia, N.Y., and Buffalo, N.Y., serving all intermediate and off-route points in Erie and Genesee Counties, N.Y.: From Batavia over New York Highway 98 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction New York Highway 33, thence over New York Highway 33 to Buffalo, and return over the same route. Between Warsaw, N.Y., and Pulaski, N.Y., serving all intermediate points and off-route points in Wyoming, Cayuga, Oswego, Genesee, and Onondaga Counties, N.Y.: From Warsaw over New York Highway 19 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction Interstate Highway 81, thence over Interstate Highway 81 to Pulaski, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga and Oswego Counties, N.Y., except those points in Cayuga County within 20 miles of Ithaca, N.Y. Between Warsaw, N.Y., to Genoa, N.Y., serving all intermediate points and off-route points in Wyoming, Cayuga, Genesee, and Livingston Counties, N.Y.: From Warsaw over New York Highway 19 to junction U.S. Highway 20, thence over U.S. Highway 20 to junction New York Highway 34, thence over New York Highway 34 to Genoa, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Livingston and Cayuga Counties, N.Y., except those points in Cayuga County within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. Between Warsaw, N.Y. to Ridgeway, N.Y., serving all intermediate and off-route points in Wyoming and Genesee Counties, N.Y.: From Warsaw over U.S. Highway 20–A to junction New York Highway 98 at Varysburg, N.Y., thence over New York Highway 98 to junction U.S. Highway 104 at Childs, N.Y., thence over U.S. Highway 104 to Ridgeway, and return over the same route. Restriction: No transportation service in the route description next-above authorized from points in Orleans County, N.Y. Between Warsaw, N.Y., and Binghamton, N.Y., serving all intermediate points and off-route points in Wyoming, Chemung, Livingston, and Broome Counties, N.Y.: From Warsaw over U.S. Highway 20–A to junction U.S. Highway 15, thence over U.S. Highway 15 to junction New York Highway 17, thence over New York Highway 17 to Binghamton, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Chemung, Broome and Livingston Counties, N.Y. except as specified in other regular routes herein. From Pine Woods, N.Y. to Batavia, N.Y., serving all intermediate and off-route points in Madison, Genesee, Onondaga, Cayuga, and Livingston Counties, N.Y.: From Pine Woods over U.S. Highway 20 to junction New York Highway 63, thence over New York Highway 63 to Batavia, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Cayuga and Livingston Counties, N.Y., except points in Cayuga County N.Y. within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. Between Buffalo, N.Y. to Ridgeway, N.Y., serving all intermediate and off-route points in Erie, Genesee and Orleans Counties, N.Y.: From Buffalo over New York Highway 5 to junction New York Highway 98 at Batavia, N.Y., thence over New York Highway 98 to junction U.S. Highway 104, thence over U.S.

Highway 104 to Ridgeway, and return over the same route.

Restriction: No transportation service in the route description next-above is authorized from points in Orleans County, N.Y. Between Buffalo, N.Y., to Albion, N.Y. serving all intermediate and off-route points in Erie, Genesee, and Orleans Counties, N.Y.: From Buffalo over New York Highway 5 to junction New York Highway 77, thence over New York Highway 77 to junction New York Highway 63, thence over New York Highway 63 to junction New York Highway 31, and thence over New York Highway 31 to Albion, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Orleans County, N.Y., From Buffalo, N.Y. and Wayland, N.Y., serving all intermediate and off-route points in Erie, Livingston, and Genesee Counties, N.Y.: From Buffalo over New York Highway 130 to junction U.S. Highway 20, thence over U.S. Highway 20 to New York Highway 15, thence over New York Highway 15 to Wayland, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Livingston County, N.Y., From Buffalo, N.Y. to Wellsville, N.Y., serving all intermediate and off-route points in Erie, Wyoming, and Allegany Counties, N.Y.: From Buffalo over New York Highway 16 to junction New York Highway 39, thence over New York Highway 39 to junction New York Highway 98, thence over New York Highway 98 to junction New York Highway 243, thence over New York Highway 243 to junction New York Highway 19, thence over New York Highway 19 to Wellsville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Allegany County, N.Y., Between Warsaw, N.Y., and Utica, N.Y. serving all intermediate and off-route points in Wyoming, Genesee, Monroe, Cayuga, Onondaga, Madison, and Oneida Counties, N.Y.: From Warsaw over New York Highway 19 to junction Interstate Highway 90, thence over Interstate Highway 90 to Utica, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga County, and to points in Madison County, N.Y., except those points in Cayuga County within 20 miles of Ithaca, N.Y. except as specified in other routes herein. Between Utica, N.Y. and Buffalo, N.Y., serving all intermediate and off-route points in Oneida, Madison, Onondaga, Cayuga, Monroe, Genesee, and Erie Counties, N.Y.: From Utica over Interstate Highway 90 to junction Exit 51 of Interstate Highway 90, thence over Exit 51 of Interstate Highway 90 to junction New York Highway 33, thence over New York Highway 33 (also over New York Highway 5 or over New York Highway 12 to junction U.S. Highway 20, thence over U.S. Highway 20 to junction New York Highway 130, thence over New York Highway 130), to Buffalo, N.Y. and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga County and to points in Madison County, N.Y., except those points in Cayuga County, N.Y. within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. Between Syracuse, N.Y. and Warsaw, N.Y., serving all intermediate and off-points in Onondaga, Cayuga, Monroe, Genesee, and Wyoming Counties, N.Y.: From Syracuse over New York Highway 690 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction New York Highway 19, thence over New York Highway 19 to Warsaw, and return over the same route.

Restriction: No transportation service in the route description next-above is authorized from points in Cayuga County except those points in Cayuga County within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. Between Syracuse N.Y., and Buffalo, N.Y. serving all intermediate and off-route points in Onondaga, Cayuga, Monroe, Genesee, and Erie Counties, N.Y.: From Syracuse over Interstate Highway 690 to junction Interstate Highway 90, (also over New York Highway 5 to junction New York Highway 96 at Waterloo, thence over New York Highway 96 to junction Interstate Highway 90), thence over Interstate Highway 90 to junction Exit 51 of Interstate Highway 90, thence over Exit 51 of Interstate Highway 90 to junction New York Highway 33, thence over New York Highway 33 to Buffalo, and return the same route.

Restriction: No transportation service in the route description next-above is authorized from points in Cayuga County, except those points within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. Between Philadelphia, Pa. and Delaware Water Gap, Pa., serving no intermediate points, serving Delaware Water Gap for the purpose of joinder only: From Philadelphia over U.S. Highway 1 to junction New Jersey Highway 31, thence over New Jersey Highway 31 to junction U.S. Highway 46, thence over U.S. Highway 46 to junction Interstate Highway 80, thence over Interstate Highway 80 (also U.S. Highway 611) to Delaware Water Gap, and return over the same route. Restriction: The authority granted in the route description next-above is restricted against transportation to, from or through New York, N.Y., and Hudson, Essex, Bergen, Sussex, Morris, Middlesex, Monmouth, Passaic, Somerset, Mercer and Union Counties, N.J. Between Philadelphia, Pa., and Townada, Pa., serving no intermediate points: From Philadelphia over Pennsylvania Highway 309 to junction Interstate Highway 276, thence over Interstate Highway 276 to junction northeast extension of Pennsylvania Turnpike, thence over northeast extension of Pennsylvania Turnpike to junction U.S. Highway 6 (also over Pennsylvania Highway 309 to junction U.S. Highway 6), thence over U.S. Highway 6 to Towanda, and return over the same route. Between Claymont, Del. and Townada, Pa., serving no intermediate points: From Claymont over U.S. Highway 13 to junction U.S. Highway 202, thence over U.S. Highway 202 to junction Pennsylvania Highway 100, thence over Pennsylvania Highway 100 to junction Pennsylvania Highway 309 thence over Pennsylvania Highway 309 to junction U.S. Highway 6, thence over U.S. Highway 6 to Townada, Pa., and return over the same route. Between Hornell, N.Y. and Mansfield, Pa., serving all intermediate points, and those off-route points within 20 miles of Wellsboro, Pa. From Hornell over New York Highway 36 to junction Pennsylvania Highway 249 at the New York-Pennsylvania State line, thence over Pennsylvania Highway 249 to junction Pennsylvania Highway 287, thence over Pennsylvania Highway 287 to junction U.S. Highway 6, thence over U.S. Highway 6 to Mansfield, and return over the same route. Between Westfield, Pa., and New York, N.Y., serving the intermediate points between Westfield, and Townada, Pa., and, for the purpose of joinder only, the intermediate points of Scranton and Delaware Water Gap, Pa., and serving intermediate and off-route points in New Jersey and New York within 20 miles of New York, N.Y. except that no transportation service is authorized to points in New York within 20 miles of New York, N.Y. except New York, N.Y., and off-route points in Potter County, Pa.:

From Westfield over PA Hwy 49 to junction PA Hwy 249, thence over PA Hwy 249 to junction PA Hwy 287, thence over PA Hwy 287 to junction US Hwy 6 at Wellsboro, thence over US Hwy 6 to junction Interstate Hwy 81, thence over

Interstate Hwy 81 to junction Interstate Hwy 380, thence over Interstate Hwy 380 to junction Interstate Hwy 80 (also from junction US Hwy 6 and US Hwy 15 at Mansfield, thence over US Hwy 15 to junction Interstate Hwy 80), thence over Interstate Hwy 80 to junction Interstate Hwy 95, thence over Interstate Hwy 95 via the George Washington Bridge to New York, and return over the same route. From Westfield, PA, to Delaware Water Gap, PA, as stated immediately above, thence over Interstate Hwy 80 to junction NJ Hwy 23, thence over NJ Hwy 23 to junction US Hwy 46, thence over US Hwy 46 to junction NJ Hwy 3, thence over NJ Hwy 3 to junction Interstate Hwy 495, thence over Interstate Hwy 495 via the Lincoln Tunnel to New York, and return over the same route. From Westfield, PA, to Delaware Water Gap, PA as stated above, thence over Interstate Hwy 80 to junction Interstate Hwy 280, thence over Interstate Hwy 280 to junction NJ Hwy 508, thence over NJ Hwy 508 to junction NJ Hwy 7, thence over NJ Hwy 7 to junction US Hwys 1 and 9, thence over US Hwys 1 and 9 to junction entrance ramp to Holland Tunnel and thence over said ramp to Holland Tunnel, thence through Holland Tunnel to New York, and return over the same route. From Westfield, PA, to Delaware Water Gap, PA, as stated above, thence over Interstate Hwy 80 to junction US Hwy 46 at Columbia, NJ, thence over US Hwy 46 to junction NJ Hwy 31, thence over NJ Hwy 31 to junction Interstate Hwy 78, thence over Interstate Hwy 78 to junction Interstate Hwy 287, thence over Interstate Hwy 287 to junction Interstate Hwy 95, thence over Interstate Hwy 95 to junction Interstate Hwy 278, thence over Interstate Hwy 278 to New York via the Goethals Bridge and return over the same route. From Westfield, PA, to Delaware Water Gap, PA, as stated above, thence over Interstate Hwy 80 to junction US Hwy 46 at Columbia, NJ, thence over US Hwy 46 to junction NJ Hwy 31, thence over NJ Hwy 31 to junction Interstate Hwy 78, thence over Interstate Hwy 78 to junction Interstate Hwy 287, thence over Interstate Hwy 287 to junction Interstate Hwy 95, thence over Interstate Hwy 95 to junction NJ Hwy 440, thence over NJ Hwy 440 via the Outerbridge Crossing to New York and return over the same route. (B) Regular routes: *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between Wellsboro, PA, and Geneva, NY, serving all intermediate points and those off-route points within 20 miles of Wellsboro, PA, and 40 miles of Ithaca, NY, provided, however, that no transportation service is authorized from off-route points beyond 20 miles of Ithaca, NY, except as specified in other regular-route or off-route points herein: From Wellsboro over PA Hwy 287 to junction US Hwy 15 at Tioga, thence over US Hwy 15 to junction PA Hwy 328, thence over PA Hwy 328 to the Pennsylvania-New York State line, thence over NY Hwy 328 to junction NY Hwy 14, thence over NY Hwy 14 to Geneva, and return over the same route. From Wellsboro over US Hwy 6 to junction US Hwy 220, thence over US Hwy 220 to junction NY Hwy 17, thence over NY Hwy 17 to junction NY Hwy 14, thence over NY Hwy 14 to Geneva, and return over the same route. From Wellsboro as stated above to junction NY Hwys 14 and 14A, thence over NY Hwy 14A to Geneva, and return over the same route.

Between Waterloo, N.Y. and Oswego, N.Y., serving all intermediate points, and those off-route points within 40 miles of Ithaca, N.Y., provided, however, that no transportation service is authorized from off-route points beyond 20 miles of Ithaca, N.Y., except as specified in other regular routes or off-route points herein: From Waterloo over New York Highway 96 to junction New York Highway 96B at Ithaca, thence over New York Highway 96B to junction New York Highway 96 at Candor, thence over New York Highway 96 to Oswego, and return over the same route. From Waterloo to Ithaca as stated immediately above, thence over New York Highway 79 to junction U.S. Highway 11 or Interstate Highway 81 thence over U.S. Highway 11 or Interstate Highway 81 to junction New York Highway 17, thence over New York Highway 17 to junction New York Highway 96, thence over New York Highway 96 (also New York Highway 17 to junction New York Highway 17C, thence over New York Highway 17C) to Oswego, and return over the same route. Between Mansfield, Pa. and Cortland, N.Y., serving all intermediate points, and those off-route points within 40 miles of Ithaca, N.Y.: From Mansfield over U.S. Highway 6 to junction Pennsylvania Highway 549, thence over Pennsylvania Highway 549 to junction Pennsylvania Highway 328, thence over Pennsylvania Highway 328 to the New York-Pennsylvania State line, thence over New York Highway 328 to junction New York Highway 13 at Elmira, thence over New York Highway 13 to Cortland, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from off-route points beyond 20 miles of Ithaca, N.Y. except as specified in other regular routes or off-route points herein. Between Buffalo, N.Y. and Binghamton, N.Y., serving all intermediate and off-route points in Erie, Genesee, Monroe, Cayuga, Onondaga, and Broome Counties, N.Y.: From Buffalo over New York Highway 130 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction exit ramp 36 of Interstate Highway 90, thence over exit ramp 36 of Interstate Highway 90 to junction Interstate Highway 81, thence over Interstate Highway 81 (also from junction of U.S. Highway 11, Interstate Highway 81 and New York Highway 281 at Tully, thence over New York Highway 281 to junction U.S. Highway 11 and Interstate Highway 81 at Cortland, and as stated above) to Binghamton, N.Y., and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga County, N.Y. except those points in Cayuga County N.Y. within 20 miles of Ithaca, N.Y. except as specified in other regular routes of off-route points herein. Between Bath, N.Y. and Dresden, N.Y., serving all intermediate points, and those off-route points within 40 miles of Ithaca, N.Y.: From Bath over New York Highway 54 to junction New York Highway 54A, thence over New York Highway 54A to junction New York Highway 54 (also over New York Highway 54) to Dresden, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from off-route points in within 20 miles of Ithaca, N.Y., except as specified in other regular routes or off-route points herein. Between Binghamton, N.Y. and Utica, N.Y., serving all intermediate and off-route points in Broome, Onondaga, Madison, and Oneida Counties, N.Y.: From Binghamton over U.S. Highway 11 (also Interstate Highway 81) to junction Interstate Highway 90 (also over Interstate Highway 90 to junction New York Highway 365, thence over New York Highway 365 to junction New York Highway 26, thence over New York Highway 26 to junction New York Highway 49, thence over New York Highway 49) (and also from Binghamton over New York Highway 12) to Utica, and return over the same route.

Restriction: No transportation service in the route description next-above is authorized from points in Broome County, N.Y. or to points Madison County, N.Y., except as specified in other regular-routes or off-route points

herein. Between Niagara Falls, N.Y., and New York, N.Y., serving the intermediate points of Scranton and Delaware Water Gap, Pa., for the purpose of joinder only and serving all intermediate and off-route points in Hudson, Essex, Bergen, Sussex, Morris and Middlesex Counties, N.J., and those in Niagara, Erie, Genesee, Wyoming, Livingston, Chemung, and Broome Counties, N.Y., provided, however, that no transportation service is authorized form points in Livingston Counties, N.Y.: From Niagara Falls, N.Y. over New York Highway 384 (also Interstate Highway 190 or U.S. Highway 62) to junction New York Highway 130 at Buffalo, N.Y., thence over New York Highway 130 to junction U.S. Highway 20 at Depew, N.Y., thence over U.S. Highway 20 to junction New York Highway 238 at Darien, N.Y., thence over New York Highway 238 to junction New York Highway 98 at Attica, N.Y., thence over New York Highway 98 to junction U.S. Highway 20 at Alexander, N.Y., thence over U.S. Highway 20 to junction U.S. Highway 15 at East Avon, N.Y., (also from Depew over U.S. Highway 20 to junction New York Highway 63, thence over New York Highway 63 to junction U.S. Highway 15 at Wayland), thence over U.S. Highway 15 to junction New York Highway 17, thence over New York Highway 17 to junction Interstate Highway 81 at Binghamton, N.Y., thence over Interstate Highway 81 to junction Interstate Highway 380, thence over Highway 380 to junction Interstate Highway 80, thence over Interstate highway 80 to junction Interstate Highway 95, thence over Interstate Highway 95 via the George Washington Bridge to New York, and return over the same route. From Niagara Falls, N.Y., to Binghamton, N.Y., as stated immediately above, thence over New York Highway 17 to junction New Jersey Highway 17 at the New York-New Jersey State line, thence over new Jersey Highway 17 to junction New Jersey Highway 4, thence over New Jersey Highway 4 to junction Interstate Highway 95, thence over Interstate Highway 95, via the George Washington Bridge to New York, N.Y., and return over the same route. From Niagara Falls, N.Y. to Binghamton, N.Y., as stated above, thence over New York Highway 17 to junction New Jersey Highway 17 at the New York-New Jersey State line, thence over New Jersey Highway 17 to junction New Jersey Highway 7, thence over New Jersey Highway 7 to junction U.S. Highways 1 and 9, thence over U.S. Highways 1 and 98 to junction entrance ramp to Holland Tunnel, thence over said entrance ramp to Holland Tunnel, thence through Holland Tunnel to New York, and return over the same route. From Niagara Falls, N.Y., to Binghamton, N.Y., as stated above, thence over New York Highway 17 to junction Interstate Highway 87 (New York Thruway), thence over Interstate Highway 87 to New York, N.Y., and return over the same route. From Niagara Falls, N.Y. to Binghamton, N.Y., as stated above, thence over New York Highway 17 at the New York-New Jersey State line, thence over New Jersey Highway 17 to New Jersey Highway 3, thence over New Jersey Highway 3 to junction Interstate Highway 495, thence over Interstate Highway 495 via the Lincoln Tunnel to New York, N.Y., and return over the same route. Between Waverly, N.Y., and Auburn, N.Y., serving all intermediate points and those off-route points within 40 miles of Ithaca, N.Y., provided, however, that no transportation service is authorized from off-route points beyond 20 miles of Ithaca, N.Y., except as specified in other regular-routes or off-route points herein: From Waverly over New York Highway 17 to junction New York Highway 35, thence over New York Highway 34 to Auburn, and return over the same route. From Waverly over New York Highway 17 to junction New York Highway 13 at Elmira, N.Y., thence over New York Highway 13 to junction New York Highway 34 at Ithaca, N.Y., thence as before to Auburn, and return over the same route.

From Waverly over New York Highway 17 to junction New York Highway 17C, thence over New York Highway 17C (also New York Highway 17 to junction New York Highway 96) to junction New York Highway 38 at Owego, N.Y., thence over New York Highway 38 to junction New York Highway 13 at Dreyden, N.Y., thence over New York Highway 13 to junction New York Highway 34 at Ithaca, N.Y., thence as stated above to Auburn, and return over the same route. From Waverly over New York Highway 17 (also New York Highway 17 to junction New York Highway 17C, thence over New York Highway 17C) to junction New York Highway 96, thence over New York Highway 96 to junction New York Highway 96B, thence over New York Highway 96B (also over New York Highway 96) to junction New York Highway 34 at Ithaca, thence as before to Auburn, and return over the same route. From Waverly as stated above to junction New York Highway 38, thence over New York Highway 38 to junction New York Highway 79 at Richford, thence over New York Highway 79 to junction New York Highway 34 at Ithaca, thence as before to Auburn, and return over the same route. From Waverly as stated above to junction New York Highway 34 and New York Highway 34B, thence over New York Highway 34B to junction New York Highway 34, thence as stated above to Auburn, and return over the same route. From Waverly over New York Highway 17 to junction New York Highway 14, thence over New York Highway 14 to junction New York Highway 224, thence over New York Highway 224 to junction New York Highway 13, thence over New York Highway 13 to junction New York Highway 34, thence as stated above (also from junction New York Highways 14 and 224, thence over New York Highway 14 to junction New York Highway 414, thence over New York Highway 414 or 14 to junction U.S. Highway 20, thence over U.S. Highway 20) to Auburn, and return over the same route. From Waverly to Ithaca as stated above, thence over New York Highway 13 to junction New York Highway 366, thence over New York Highway 366 to junction New York Highway 38, thence over New York Highway 38 to Auburn, and return over the same route. Service over routes in (B) above is authorized at the additional off-route points of Chenango Bridge, Chenango Forks, Akron, Amherst, Blasdell, Clarence Center, Depew, E. Aurora, Hamburg, Jewettville, Kenmore, Lackawanna, Orchard Park, Sloan, Snyder, Williamsville, Breesport, Erin, Pine City, Southport, Van Etten, Webbsmills, Wellsburg, Burdett, Cayuta, Odessa, Addison, Arkport, Campbell, Canisteo, Erwins, Greenwood, Hornell, Jaspen, N. Hornell, Presho, Rheims, Woodhull, McGraw, Preble, Candor, Spencer, Groton, Ludlowville, Myers, North Lansing, South Lansing, Trumansburg, Howard, Aurora, Cayuga, Kandaia, Lodi, MacDougall, Sampson, Union, Springs, and Willard, N.Y. (C) Regular Routes: *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), Between Auburn, N.Y., and Syracuse, N.Y., serving all intermediate and off-route points in Onondaga, and Cayuga Counties, N.Y.: From Auburn over New York Highway 5 (also over U.S. Highway 20 to junction unnumbered highway at Skaneateles, thence over unnumbered highway to junction New York Highway 175, thence over New York Highway 175) to Syracuse, and return over the same route. Restriction: no transportation service in (C) above is authorized from points in Cayuga County, N.Y., except from points in

Cayuga County, N.Y. within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein.

Between Brockport, PA, and Williamsport, PA, serving all intermediate points, and those off-route points in Elk, Cameron, and Potter Counties, PA, except points in Elk and Cameron County, PA, on the one hand, and, on the other, Williamsport, PA, and points within a 5 mile radius of Williamsport: From Brockport over U.S. Highway 219 to junction PA Hwy 120 at Ridgeway, PA, thence over PA Hwy 120 to junction U.S. Highway 220 at Lock Haven, thence over U.S. Highway 220 to Williamsport, and return over the same route. Between Brockport, PA, and Bradford, PA, serving all intermediate points, and those off-route points within 30 miles of Bradford, PA: From Brockport over U.S. Highway 219 to Bradford, and return over the same route. Between Brockport, PA, and Wellsboro, PA, serving all intermediate points and those off-route points in Elk, Cameron, Potter, and Tioga Counties, PA, and points within 20 miles of Wellsboro: From Brockport over U.S. Highway 219 to junction PA Hwy 120 at Ridgeway, PA, thence over PA Hwy 120 to junction PA Hwy 155, thence over PA Hwy 155 to junction U.S. Highway 6, thence over U.S. Highway 6 to Wellsboro, and return over the same route. Between Bradford, PA, and Wellsboro, PA, serving all intermediate and off-route points within 30 miles of Bradford, PA, and 20 miles of Wellsboro, PA, those points in Allegany and Chemung Counties, NY, and Tioga County, PA, and the points of Greenwood, Jasper, Woodhull, Addison, Erwins, and Presho, NY: From Bradford over U.S. Highway 219 to junction NY Hwy 17, thence over NY Hwy 17 to junction NY Hwy 417, thence over NY Hwys 17 or 417 to junction U.S. Highway 15, thence over U.S. Highway 15 to junction PA Hwy 287, thence over PA Hwy 287 to Wellsboro, and return over the same route. From Bradford to junction U.S. Highway 15 as stated above and PA Hwy 287, thence over U.S. Highway 15 to junction U.S. Highway 6, thence over U.S. Highway 6 to Wellsboro, and return over the same route. From Brandford over PA Hwy 346 to junction PA Hwy 646, thence over PA Hwy 646 to the PA–NY State line, thence over NY Hwy 16 to junction NY Hwy 417 or NY Hwy 17, thence as stated above to Wellsboro, and return over the same route. From Bradford to NY Hwy 17 or NY Hwy 417 as stated above, thence over NY Hwy 17 or NY Hwy 417 to junction NY Hwy 19, thence over NY Hwy 19 to junction PA Hwy 449 at the NY–PA State line, thence over PA Hwy 449 to junction U.S. Highway 6, thence over U.S. Highway 6 to Wellsboro, and return over the same route. Between Bradford, PA, and Williamsport, PA, serving all intermediate points and off-route points within 30 miles of Bradford, 20 miles of Wellsboro and those points in Elk, Potter, Cameron, and Tioga Counties, PA, except points in Elk and Cameron Counties, PA, on the one hand, and, on the other, Williamsport, PA, and points within a 5 mile radius Williamsport: From Bradford over U.S. Highway 219 to junction PA Hwy 46, thence over PA Hwy 46 to junction U.S. Highway 120, thence over U.S. Highway 120 to junction U.S. Highway 220 at Lock Haven, thence over U.S. Highway 220 (also over PA Hwy 46 to junction U.S. Highway 6, thence over U.S. Highway 6 to junction U.S. Highway 15, thence over U.S. Highway 15) to Williamsport, and return over the same route. Between Bradford, PA, and Williamsport, PA, serving intermediate and off-route points within 30 miles of Bradford, those points in Allegany and Chemung Counties, NY, and Tioga County, PA, and the points of Greenwood, Jasper, Woodhul, Addison, Erwins, and Presho, NY, all intermediate and off-route points within 20 miles of Wellsoboro, PA, and 5 miles of Williamsport:

From Bradford over U.S. Highway 219 to junction New York Highway 17, thence over New York Highway 17 to junction U.S. Highway 15, (also from the junction of U.S. Highway 219 and New York Highway 17 over New York Highway 17 to junction New York Highway 14, thence over New York Highway 14 to junction Pennsylvania Highway 14 to junction U.S. Highway 15), thence over U.S. Highway 15 to Williamsport, and return over the same route. Between Claymont, Del. and Williamsport, Pa., serving intermediate and off-route points within 5 miles of Williamsport, Pa.: From Claymont over U.S. Highway 13 to junction U.S. Highway 202, thence over U.S. Highway 202 to junction Pennsylvania Highway 100 thence over Pennsylvania Highway 100 to junction U.S. Highway 422, thence over U.S. Highway 422 to junction Pennsylvania Highway 61, thence over Pennsylvania Highway 61 to junction U.S. Highway 15, thence over U.S. Highway 15 to Williamsport, and return over the same route. Between Philadelphia, Pa., and Williamsport, Pa., serving the intermediate and off-route points within 5 miles of Williamsport, Pa.: From Philadelphia over U.S. Highway 422 to junction Interstate Highway 61, thence over Pennsylvania Highway 61 to junction U.S. Highway 15, thence over U.S. Highway 15 to Williamsport, and return over the same route. From Philadelphia over Pennsylvania Highway 309 to junction Interstate Highway 81, thence over Interstate Highway 81 to junction Pennsylvania Highway 93, thence over Pennsylvania Highway 93 to junction Interstate Highway 80, thence over Interstate Highway 80 to junction U.S. Highway 15, thence over U.S. Highway 15 to Williamsport and return over the same route. Between Wellsboro, Pa., and Williamsport, Pa., serving intermediate points and off-route points within 20 miles of Wellsboro, Pa., and 5 miles of Williamsport, Pa.: From Wellsboro over U.S. Highway 6 to junction U.S. Highway 15, thence over U.S. Highway 15 to Williamsport, and return over the same route. From Wellsboro over U.S. Highway 6 to junction Pennsylvania Highwy 660, thence over Pennsylvania Highway 660 to junction U.S. Highway 6, thence as stated above to Williamsport, and return over the same route. From Wellsboro over Pennsylvania Highway 287 to junction U.S. Highway 220, thence over U.S. Highway 220 to Williamsport, and return over the same route. From Wellsboro over Pennsylvania Highway 287 to junction Pennsylvania Highway 414, thence over Pennsylvania Highway 414 to junction U.S. Highway 15, thence as stated above to Williamsport, and return over the same route. Between Jamestown, N.Y., and junction U.S. Highway 219, and New York Highway 17, serving all intermediate and those off-route points within 30 miles of Bradford, Pa.: From Jamestown over New York Highway 17 to junction U.S. Highway 219, and return over the same route. Between Jamestown, N.Y. and Wellsboro, Pa., serving all intermediate points and those off-route points within 30 miles of Bradford, Pa., and within 20 miles of Wellsboro, Pa.: From Jamestown over New York Highway 60 to junction U.S. Highway 62, thence over U.S. Highway 62 to junction U.S. Highway 6 at Warren, Pa., thence over U.S. Highway 6 to Wellsboro, Pa., and return over the same route.

Between Warren, Pa., and Portville, N.Y., serving all intermediate points, and those off-route points within 30 miles of Bradford, Pa.: From Warren over Pennsylvania Highway 59 to junction U.S. Highway 6 at Smethport, thence over U.S. Highway 6 to junction Pennsylvania Highway 446, thence over Pennsylvania Highway 446 to the New York-Pennsylvania State line, thence over New York Highway 305 to junction New York Highway 417, thence over New York Highway 417 to Portville, and return over the same route. Between

Coudersport, Pa., and Lawrenceville, Pa., serving all intermediate points and off-route points in Potter County, Pa., points within 20 miles of Wellsboro, Pa.: From Coudersport over Pennsylvania Highway 44 to junction Pennsylvania Highway 49, thence over Pennsylvania Highway 49 to Lawrenceville, and return over the same route. Between Ceres, N.Y., and Coudersport, Pa., serving all intermediate points and off-route points in Potter County, Pa., and those points within 30 miles of Bradford, Pa.: from Ceres at the New York-Pennsylvania State line over Pennsylvania Highway 44 to Coudersport, Pa., and return over the same route. From Buffalo, N.Y., to Brockport, Pa., serving intermediate and off-route points in Erie and Allegany Counties, N.Y., and those in Elk Potter and Cameron Counties, Pa.: From Buffalo over New York Highway 400 to junction New York Highway 16 (also over New York Highway 16), thence over New York Highway 16 to junction New York Highway 417, thence over New York Highway 417 to junction New York Highway 305, thence over New York Highway 305 to the New York-Pennsylvania State line, thence over Pennsylvania Highway 446 to junction Pennsylvania Highway 346, thence over Pennsylvania Highway 346 to junction U.S. Highway 219, thence over U.S. Highway 219 (also over U.S. Highway 219 from Buffalo) to Brockport, and return over the same route. Between Rochester, N.Y., and Niagara Fall, N.Y., serving intermediate and off-route points in Monroe, Orleans, and Niagara Counties, N.Y.: From Rochester over New York Highway 104 to Niagara Falls, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Orleans County, N.Y. Between Rochester, N.Y. and Buffalo, N.Y., serving intermediate and off-route points in Monroe, Genesee, and Erie Counties, N.Y.: From Rochester over Interstate Highway 490 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction New York Highway 33, thence over New York Highway 33 to Buffalo, and return over the same route. Between Rochester, N.Y., and Syracuse, N.Y., serving intermediate and off-route points in Monroe, Cayuga, and Onondaga Counties, N.Y.: From Rochester, N.Y. over Interstate Highway 490 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction exits 35 through 38 of Interstate Highway 90, thence over appropriate exits to Syracuse, N.Y., and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga County, N.Y. execpt those points within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. From Rochester, N.Y., to Medina, N.Y., serving intermediate and off-route points in Orleans and Monroe Counties, N.Y.: From Rochester over New York Highway 104 to junction New York Highway 63 at Ridgeway, thence over new York Highway 63 to Medina, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Orleans County, N.Y.

Between Rochester, N.Y. and Binghamton, N.Y., serving all intermediate and off-route points in Broome, Chemung, Livingston, and Monroe Counties, N.Y.: From Rochester over U.S. Highway, 15 to junction New York Highway 17, thence over New York Highway 17 (also New York Highway 17C) to, Binghamton, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Broome, Chemung, and Livingston Counties, N.Y., except as specified in other regular-route herein. Between Rochester, N.Y. and Utica, N.Y., serving intermediate and off-route points in Cayuga, Madison, Monroe, Oneida, and Onondaga Counties, N.Y.: From Rochester, over Interstate Highway 490 to junction Interstate Highway 90, thence over Interstate Highway 90 to Utica, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y. and from points in Cayuga County, N.Y., except those points in Cayuga County within 20 miles of Ithaca, N.Y. except as specified in other regular routes herein. From Rochester, N.Y. to Oswego, N.Y., serving intermediate and off-route points in Monroe, Cayuga, and Oswego Counties, N.Y.: From Rochester, over U.S. Highway 104 to Oswego, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga and Oswego Counties, N.Y., except those points within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. From Rochester, N.Y. to Wellsville N.Y. serving intermediate points and off-route points in Monroe, Livingston, and Allegany Counties, N.Y.: From Rochester over U.S. Highway, 15 (also U.S. Highway 15A) to junction New York Highway 21, thence over New York Highway 21 to junction New York Highway 417 at Andover, thence over New York Highway 417 to Wellsville, and return over the same route. Restriction: No transportation in the next-above route description is authorized from points in Livingston and Allegany Counties, N.Y. From Batavia, N.Y. to Dansville, N.Y., serving intermediate and off-route points in Genesee, Wyoming, and Livingston Counties, N.Y.: From Batavia over New York Highway 63 to Dansville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Livingston County, N.Y. From Batavia, N.Y. to Wellsville, N.Y., serving intermediate and off-route points in Genesee, Wyoming, and Allegany Counties, N.Y.: From Batavia over New York Highway 63 to junction New York Highway 19, thence over New York Highway 19 to Wellsville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Allegany County, N.Y. From Utica, N.Y. to Dansville, N.Y. serving intermediate and off-route points in Oneida, Madison, Onondaga, Cayuga, and Livingston Counties, N.Y.: From Utica over Interstate Highway 90 to junction U.S. Highway 15, thence over U.S. Highway 15, to junction Interstate Highway 390, thence over Interstate Highway 390 to Junction New York Highway 436, thence over New York Highway 436 to Dansville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County or from points in Cayuga and Livingston Counties, N.Y., except those points in Cayuga County, N.Y. within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. From Utica, N.Y., to Wellsville, N.Y., serving intermediate and off-route points in Oneida, Madison, Onondaga, Cayuga, Chemung, and Allegany counties, N.Y.:

From Utica over Interstate Highway 90 to junction New York Highway 14, thence over New York Highway 14 to junction New York Highway 414, thence over New York Highway 414 to junction New York Highway 17, thence over New York Highway 17 to junction U.S. Highway 15, thence over U. S. Highway 15 to junction New York Highway 417, thence over New York Highway 417 to Wellsville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y. or from points in Cayuga, Chemung, and Allegany Counties, N.Y. except those points in Cayuga and Chemung Counties, N.Y.

within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. From Syracuse, N.Y., to Dansville, N.Y., serving intermediate and off-route points in Onondaga, Cayuga, and Livingston Counties, N.Y.: From Syracuse over Interstate Highway 81 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction New York Highway 21, thence over New York Highway 21 to junction New York Highway 63, thence over New York Highway 63 to Dansville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Cayuga and Livingston Counties, N.Y. except points in Cayuga County, N.Y. within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. From Syracuse, N.Y., to Wellsville, N.Y., serving intermediate and off-route points in Onondaga, Chemung, and Allegany Counties, N.Y.: From Syracuse over Interstate Highway 81 (also U.S. Highway 11) to junction New York Highway 13, thence over New York Highway 13 to junction New York Highway 17, thence over New York Highway 17 to junction U.S. Highway 15, thence over U.S. Highway 15 to junction New York Highway 417, thence over New York Highway 417 to Wellsville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Chemung and Allegany Counties, N.Y. except points in Chemung County, N.Y. within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. From Warsaw, N.Y., to Dansville, N.Y., serving intermediate and off-route points in Wyoming and Livingston Counties, N.Y.: From Warsaw over U.S. Highway 20A to junction New York Highway 36, thence over New York Highway 36 to junction New York Highway 436, thence over New York Highway 436 to Dansville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Livingston County, N.Y. From Warsaw, N.Y. to Wellsville, N.Y., serving intermediate and off-route points in Wyoming and Allegany Counties, N.Y.: From Warsaw over New York Highway 19 (also New York Highway 19A) to Wellsville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Allegany County, N.Y. From Hamilton, N.Y., to Dansville, N.Y., serving intermediate and off-route points in Madison, Onondaga, Cayuga, and Livingston Counties, N.Y.: From Hamilton over New York Highway 12B to junction U.S. Highway 20, thence over U.S. Highway 20 to junction New York Highway 21, thence over New York Highway 21 to junction New York Highway 63, thence over New York Highway 63 to Dansville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized from points in Madison County, N.Y., or from points in Cayuga and Livingston Counties, N.Y., except those points in Cayuga County N.Y. within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein.

From Hamilton, N.Y., to Wellsville, N.Y., serving intermediate and off-route points in Madison, Broome, Chemung, and Allegany Counties N.Y.: From Hamilton over New York Highway 12B to junction New York Highway 12, thence over New York Highway 12 to junction New York Highway 17, thence over New York Highway 17 to junction U.S. Highway 15, thence over U.S. Highway 15 to junction New York Highway 417, thence over New York Highway 417 to Wellsville, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y., or from points in Broome, Chemung, and Allegany Counties, N.Y., except those points in Broome and Chemung Counties, N.Y. within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. Between Hamilton, N.Y., and Warsaw, N.Y., serving intermediate and off-route points in Madison, Onondaga, Cayuga, Livingston, and Wyoming Counties, N.Y.: From Hamilton over New York Highway 12B to junction U.S. Highway 20, thence over U.S. Highway 20 to junction U.S. Highway 20A, thence over U.S. Highway 20A to Warsaw, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y. or from points in Cayuga and Livingston Counties, N.Y. except those points in Cayuga County, N.Y. within 20 miles of Ithaca, N.Y. except as specified in other regular-routes herein. Between Hamilton, N.Y. and Niagara Falls, N.Y., serving intermediate and off-route points in Madison, Onondaga, Cayuga, Monroe, Genesee, Erie, and Niagara Counties, N.Y.: From Hamilton over New York Highway 12B to junction U.S. Highway 20, and thence over U.S. Highway 20 to junction New York Highway 318, thence over New York Highway 318 to junction New York Highway 414, thence over New York Highway 414 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction Interstate Highway 290, thence over Interstate Highway 290 to junction Interstate Highwy 190, thence over Interstate Highway 190 (also New York Highways 265 and 384) to Niagara Falls, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y., or from points in Cayuga County, N.Y., except those points in Cayuga County, N.Y. within 20 miles of Ithaca, N.Y., except as specified in other regular-routes herein. From Hamilton, N.Y., to Rome, N.Y., serving the intermediate and off-route points in Madison and Oneida Counties, N.Y.: From Hamilton over New York Highway 12B to junction New York Highway 46, thence over New York Highway 46 to junction U.S. Highway 5, thence over U.S. Highway 5 to junction New York Highway 365, thence over New York Highway 365 to junction New York Highway 26, thence over New York Highway 26 to Rome, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y. From Hamilton, N.Y., to Medina, N.Y., serving intermediate and off-route points in Madison, Onondaga, Cayuga, Monroe, and Orleans Counties, N.Y.: From Hamilton over New York Highway 12B to junction U.S. Highway 20, thence over U.S. Highway 20 to junction New York Highway 318, thence over New York Highway 318 to junction New York Highway 414, thence over New York Highway 414 to junction Interstate Highway 90, thence over Interstate Highway 90 to junction Interstate Highway 490, thence over Interstate Highway 490 to junction New York Highway 47, thence over New York Highway 47 to junction New York Highway 31, thence over New York Highway 31 (also New York Highway 31A) to Medina, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y. or from points in Cayuga and Orleans Counties, N.Y. except those points in Cayuga County, N.Y. within 20 miles of Ithaca, N.Y. From Hamilton, N.Y., to Oswego, N.Y., serving intermediate and off-route points in Madison, Onondaga, and Oswego Counties, N.Y.

From Hamilton over New York Highway 12B to junction U.S. Highway 20, thence over U.S. Highway 20 to junction Interstate Highway 81 (also U.S. Highway 11), thence over Interstate

Highway 81 to junction New York Highway 481, thence over New York Highway 481 to junction New York Highway 57, thence over New York Highway 57 to Oswego, and return over the same route. Restriction: No transportation service in the route description next-above is authorized to points in Madison County, N.Y. or from points in Oswego County, N.Y. Between New York, N.Y., and Buffalo, N.Y., serving the intermediate points between Utica and Buffalo, N.Y.: From New York over Interstate Highway 87 to junction Interstate Highway 90, thence over Interstate Highway 90 to Buffalo, and return over the same route. Alternate Routes for Operating Convenience Only: *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), Between Rochester, N.Y., and Akron, N.Y., in connection with carrier's regular route operations, serving no intermediate points: From Rochester, N.Y. over Interstate Highway 490 to junction New York Highway 19, thence over New York Highway 19 to LeRoy, N.Y., and thence over New York Highway 5 to junction with New York Highway 93, and thence over New York Highway 93 to Arkon, N.Y., and return over the same route. Between Binghamton, N.Y., and Scranton Pa., serving no intermediate points: From Binghamton over Interstate Highway 81 to Scranton, Pa., and return over the same route. Between Delaware Water Gap, Pa., and Somerville, N.J., serving no intermediate points: From Delaware Water Gap over Interstate Highway 80 to junction U.S. Highway 46 at Columbia, N.J., thence over U.S. Highway 46 to junction New Jersey Highway 31, thence over New Jersey Highway 31 to junction Interstate Highway 78, thence over Interstate Highway 78 to junction U.S. Highway 22, thence over U.S. Highway 22 to junction New Jersey Highway 28, thence over New Jersey Highway 28 (also from junction U.S. Highway 22 and U.S. Highway 206 or local streets) to Somerville, and return over the same route. Between Brockport, Pa., and Delaware Water Gap, Pa., serving no intermediate points: From Brockport over U.S. Highway 219 to junction Interstate Highway 80, thence over Interstate Highway 80 to Delaware Water Gap, and return over the same route. Between Williamsport, Pa., and Delaware Water Gap, Pa., serving no intermediate points: From Williamsport over U.S. Highway 15 to junction Interstate Highway 80, thence over Interstate Highway 80 to Delaware Water Gap, and return over the same route. Restriction: The alternate routes above between Carroll, Pa., and DuBois, Pa., over Interstate Highway 80 and the regular route between Lock Haven, Pa. and Ridgeway, Pa. over Pennsylvania Highway 120 is restricted against the transportation of traffic moving to, from, or through Pittsburgh, Pa. and points in the Pittsburgh Commercial Zone. Irregular Routes: *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), Between points in Wyoming County, N.Y. Between points in Erie County, N.Y. The irregular-route authority granted above is issued pursuant to an application filed after November 23, 1973, and in accordance with 49 CFR 1065 may not be tacked or joined with the carrier's other irregular-route authority unless specifically authorized herein.

Restriction: The above described regular and irregular routes in (A), (B) and (C) above shall not be severable by sale or otherwise from the regular and irregular route general commodity authority set forth in (D) and (E) below. (D) Regular Routes: *General commodities* (except classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), (1) Between Ithaca, N.Y., and Syracuse, N.Y., serving all intermediate points: From Ithaca over New York Highway 13 to Cortland, N.Y., thence over U.S. Highway 11 to Syracuse, and return over the same route. From Ithaca over New York Highway 13 to South Cortland, N.Y., thence over New York Highway 281 to junction U.S. Highway 11 near Tully, N.Y., thence over U.S. Highway 11 to Syracuse, and return over the same route. (2) Between Auburn, N.Y., and Syracuse, N.Y., serving all intermediate points: From Auburn over New York Highway 5 to Syracuse, and return over the same route. From Auburn over U.S. Highway 20 to Skaneateles, N.Y., thence over unnumbered highway to Macellus, N.Y., thence over New York Highway 175 (also over New York Highway 20N) to Syracuse, and return over the same routes. (3) Between Ithaca, N.Y., and Waverly, N.Y., serving all intermediate points, and the off-route points of Cayuga, Millport, Pine Valley, and Wellsburg, N.Y.: From Ithaca over New York Highway 79 to Richford, N.Y., thence over New York Highway 38 to Oswego, N.Y., thence over New York Highway 17 to Waverly, and return over the same route. From Ithaca over New York Highway 96B to Candor, N.Y., thence over New York Highway 96 to Oswego, thence over New York Highway 17 to Waverly, and return over the same route. From Ithaca over New York Highway 13 to Elmira, N.Y., thence over New York Highway 17 to Waverly, and return over the same route. From Ithaca over New York Highway 13 to junction New York Highway 34, thence over New York Highway 34 to Waverly, and return over the same route. Restriction: The operations authorized under (3) above are restricted to service between the authorized points on said routes, on the one hand, and, on the other, points on routes (1) and (2) above. (4) Between Ithaca, N.Y., and Auburn, N.Y., serving all intermediate points: From Ithaca over New York Highway 96 to Waterloo Junction, N.Y., thence over U.S. Highway 20 (also over New York Highway 5) to Auburn, and return over the same routes. Service on the route described immediately-above is authorized at the off-route points of Lodi, Willard, Kandaia, Sampson, and MacDougall, N.Y. From Ithaca over New York Highway 34 to Auburn, and return over the same route. From Ithaca over New York Highway 34 to junction New York Highway 34B, thence over New York Highway 34B to junction New York Highway 34 at Fleming, N.Y., thence over New York Highway 34 to Auburn, and return over the same route. Service over the two route descriptions next-above is authorized at the off-route points of Aurora, Union Springs, and Cayuga, N.Y. From Ithaca over New York Highway 13 to junction New York Highway 366, thence over New York Highway 366 to junction New York Highway 38, thence over New York Highway 38 to Auburn, and return over the same route.

Restriction: The operations authorized under (4) above are restricted to service between the authorized points on said routes, on the one hand, and, on the other, points on routes (1) and (2) above. (5) Between Ithaca, N.Y., and Watkins Glen, N.Y., serving all intermediate points; From Ithaca over New York Highway 13 to junction New York Highway 224, thence over New York Highway 224 to Watkins Glen, and return over the same route. Restriction: The operations authorized on the route next above is restricted to service between the authorized points on said routes, on the one hand, and, on the other, points on routes (1) and (2) above. *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission,

commodities in bulk, and commodities requiring special equipment), Between Niagara Falls, N.Y., and Binghamton, N.Y. serving all intermediate points, except the intermediate points between Buffalo and Wayland, N.Y.: From Niagara Falls over New York Highway 384 to Buffalo, N.Y., thence over New York Highway 130 to junction U.S. Highway 20, thence over U.S. Highway 20 to junction New York Highway 63; thence over New York Highway 63 to Wayland, N.Y., thence over U.S. Highway 15 to Painted Post, N.Y., and thence over New York Highway 17 to Binghamton (also from Big Flats, N.Y. and Elmira, N.Y. over New York Highway 352 (formerly New York Highway 17E) to junction New York Highway 17) (also from Oswego, N.Y., over New York Highway 17C to Binghamton), and return over the same routes. Between Corning, N.Y., and Binghamton, N.Y., serving all intermediate points: From Corning over New York Highway 17 to Horseheads, N.Y., thence over New York Highway 13 to Cortland, N.Y., and thence over U.S. Highway 11 to Binghamton, and return over the same route. Between Bath, N.Y., and Elmira, N.Y., serving all intermediate points: From Bath over New York Highway 54 (also over New York Highway 54A to junction New York Highway 54) to Dresden, N.Y., thence over New York Highway 14 (also from Penn Yan, N.Y., over New York Highway 14A to junction New York Highway 14) to Horseheads, N.Y., thence over New York Highway 13 (also from Horseheads over New York Highway 17) to Elmira, and return over the same routes. Between Buffalo, N.Y., and Homer, N.Y., serving no intermediate points: From Buffalo over New York Highway 130 to junction U.S. Highway 20, thence over U.S. Highway 20 to junction U.S. Highway 11, thence over U.S. Highway 11 to Homer, and return over the same route. Service over the 4 specified routes next-above is authorized at the off-route points of Chenango Bridge, Chenango Forks, Akron, Amherst, Blasdell, Clarence Center, Depew, E. Aurora, Hamburg, Jewettville, Kenmore, Lackawanna, Orchard Park, Sloan, Snyder, Williamsville, Breesport, Erin, Pine City, Southport, Van Etten, Webbsmills, Wellsburg, Burdett, Cayuga, Odessa, Addison, Arkport, Campbell, Canisteo, Erwins, Greenwood, Hornell, Howard, Jasper, N. Hornell, Presho, Rheims, Woodhull, McGraw, Preble, Candor, Spencer, Groton Ludlowville, Myers, North Lansing, South Lansing, and Trumansburg, N.Y.; Between Williamsport, Pa., and Bradford, Pa., serving all intermediate points, and points within 5 miles of Williamsport and all points in Tioga County, Pa., as off-route points: From Williamsport over U.S. Highway 15 to junction U.S. Highway 6 at Mansfield, Pa., thence over U.S. Highway 6 to junction Pennsylvania Highway 46 in Smethport, Pa., thence over Pennsylvania Highway 46 to junction Pennsylvania Highway 346 and thence over Pennsylvania Highway 346 to Bradford, and return over the same route. Restriction: No local shipments in the route description next-above shall be transported between Blossburg and Mansfield, Pa., and points intermediate thereto on U.S. Highway 15.

General commodities (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and articles of excessive dimensions), Between Ithaca, NY, and Syracuse, NY, serving all intermediate points, and the off-route point of Preble, NY: From Ithaca over NY Hwy 13 to Cortland, NY, thence over U.S. Hwy 11 to Syracuse, and return over the same route. Irregular Routes: *General commodities* (except those of unusual value, classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), Between Bradford, PA, and points within 30 miles of Bradford, on the one hand, and, on the other, points in Elk, Potter, and Cameron Counties, PA. Restriction: The service authorized in the route description next-above is subject to the following conditions: The authority granted in the route description next-above is restricted against service between points in Elk and Cameron Counties, PA, on the one hand, and, on the other, Williamsport, PA, and points within a 5 mile radius of Williamsport. The authority granted in the route description next-above is restricted against the transportation of bricks, clay products and refactory products from the plant site of the Hanley Company at Lewis Run, PA, to points in Ohio and New York. *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities requiring special equipment, and commodities in bulk), Between Wellsboro, PA, on the one hand, and, on the other, Troy and Townada, PA, and points with 20 miles of Wellsboro. Between Westfield, PA, on the one hand, and, on the other, New York, NY, and points in New Jersey within 20 miles of New York, NY, Philadelphia, PA, and Claymont, Del. From New York, NY, and points in that part of New York and New Jersey within 20 miles of New York, NY, to Wellsboro, PA. From Ithaca, NY, and points within 20 miles of Ithaca, to New York, NY, and points in Hudson, Essex, Bergen, Sussex, Morris and Middlesex Counties, NJ. From New York, NY, and points in Hudson, Essex, Bergen, Sussex, Morris, and Middlesex Counties, NJ, to Ithaca, NY, and points within 40 miles of Ithaca. Between points in Wyoming County, NY. Between points in Erie County, NY. From points in Wyoming County, NY, to points in Broome, Cayuga, Chemung, Erie, Genesee, Monroe, Niagara, Oneida, Orleans, and Oswego Counties, NY. From points in Erie, Genesee, Monroe and Onondaga Counties, NY, to points in Wyoming County, NY. From points in Erie County, NY, to points in Allegany, Genesee, Livingston, Onondaga, and Orleans Counties, NY. From points in Genesee, Oneida, and Onondaga Counties, NY, to points in Erie County, NY. From points in Madison and Niagara Counties, NY, to points in Genesee County, NY.

Glass bottles, From Port Allegany, Pa., to Baltimore, Md. *Uncrated machinery,* From Waterville, New Berlin, and New York, N.Y., to Middlebury Center, Pa.; and *Dairy products,* From Middlebury Center, Pa., to Waterville, New Berlin, and New York, N.Y. *Manufactured glass products,* or *articles used in the manufacture, sale or distribution thereof,* Between Wellsboro, Pa., and Corning, N.Y., on the one hand, and, on the other, Central Falls, R.I., Lynn, Newburyport, Newton, Salem and Waltham, Mass., Schenectady, N.Y., Charleroi, Lancaster, Lansdale, and Port Allegany, Pa., Cleveland, Warren and Youngstown, Ohio, and Fairmont and Parkersburg, W. Va. Between Corning, N.Y., on the one hand, and, on the other Weatherly and Boyertown, Pa. Between Wellsboro, Pa., and Corning, N.Y. *Manufactured glass products* (except glass tubing and unfinished light and radio bulbs), From Wellsboro, Pa., and Corning, N.Y., to New York, N.Y., and points in that part of New York and New Jersey within 20 miles of New York, N.Y. *Unfinished light and radio bulbs,* and *glass tubing,* From Wellsboro, Pa., and Corning, N.Y., to points in New York and that part of New Jersey on and north of U.S. Highway 40; and *Packing materials and cases,* From points in the next-above specified New York and New Jersey territory to Wellsboro, Pa., and Corning, N.Y. *Petroleum products,* in containers, From Sewaren, N.J., to Wellsboro, Pa.; and *Empty containers for petroleum products,* From Wellsboro, Pa., to Sewaren, N.J. (E) Irregular

Routes: *General commodities* (Except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), From points in Erie, Genesee, and Onondaga Counties, N.Y., to points in Broome, Cayuga, Chemung, Oneida and Oswego Counties, N.Y. From points in Erie and Genesee Counties, N.Y., to points in Niagara County, N.Y. From points in Genesee and Onondaga Counties, N.Y., to points in Orleans County, N.Y. From points in Oneida and Onondaga Counties, N.Y., to points in Genesee County, N.Y. Between points in Genesee, and Monroe Counties, N.Y., From points in Genesee, Oneida and Onondaga Counties, N.Y., to points in Onondaga County, N.Y. From points in Oneida County, N.Y., to points in Wyoming County, N.Y. From points in Wyoming County, N.Y., to points in Onondaga County, N.Y. From points in Niagara County, N.Y., to points in Erie and Wyoming Counties, N.Y. From points in Onondaga County, N.Y., to points in Niagara County, N.Y. From points in Oneida County, N.Y., to points in Broome, Cayuga, Chemung, Monroe, Niagara, Oneida, Orleans, and Oswego Counties, N.Y. From points in Niagara County, N.Y., to points in Broome, Cayuga, Chemung, Niagara, Oneida, Orleans, and Oswego Counties, N.Y. From points in Niagara County, N.Y., to points in Onondaga County, N.Y. Between points in Monroe County, N.Y., on the one hand, and, on the other, points in Niagara, Erie and Onondaga Counties, N.Y. From points in Monroe County, N.Y., to points in Broome, Cayuga, Chemung, Oneida, Orleans, and Oswego Counties, N.Y. From points in Genesee, Oneida, Onondaga, and Wyoming Counties, N.Y., to points in Livingston and Allegany Counties, N.Y. From points in Madison and Niagara Counties, N.Y., to points in Livingston and Allegany Counties, N.Y. From points in Monroe County, N.Y., to points in Livingston and Allegany Counties, N.Y. From points in Madison County, N.Y., to points in Erie County, N.Y. From points in Madison County, N.Y., to points in Onondaga and Wyoming Counties, N.Y. From points in Madison County, N.Y., to points in Broome, Cayuga, Chemung, Monroe, Niagara, Oneida, Orleans, and Oswego Counties, N.Y. The authority granted in (E) above is issued pursuant to an application filed after November 23, 1973, and in accordance with 49 CFR 1065 may not be tacked or joined with the carrier's other irregular-route authority unless specifically authorized herein. Restriction; Carrier shall not, pursuant to the irregular-route authority granted in (D) and (E) authorized to be served by it in the operations authorized in (A), (B) and (C) above. Any repetition in the statement of the authority granted herein shall not be construed as conferring more than one operating right. MC–109821 Sub 40 authorizes transportation, over irregular routes, of *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), Between Bradford, Pa., and points within 30 miles thereof, on the one hand, and, on the other, Philadelphia and Pittsburgh, Pa. *Commodities,* classified as "meats, meat products, and meat by-products" in Section A of the Appendix to the report in Ex Parte 38, *Modification of Permits of Motor Contract Carriers of Packing House Products,* 46 M.C.C. 23, butter, and cheese, From Punxsutawney and Du Bois, PA., to Kane and Phillipsburg, PA., and points in Cameron, Clarion, Clearfield, Elk, Forest and Jefferson Counties, PA. *General commodities,* except classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment, Between Big Run, Jefferson County, PA., and points within 25 miles of Big Run, on the one hand, and, on the other, Pittsburgh and Philadelphia, PA. This certificate is issued pursuant to an application filed after November 23, 1973, and in accordance with 49 CFR 1065 may not be tacked or joined with the carrier's other irregular-route authority unless specifically authorized herein. MC–109821 Sub 53 authorizes transportation, over regular routes, of *General commodities* (except articles of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), Between Big Run, Jefferson County, PA, and Philadelphia, PA., serving points within 25 miles of Big Run as intermediate and/or off-route points, and points in Elk, Potter, Tioga, and Cameron Counties, PA, as off-route points: (A) From Big Run over US Highway 119 to junction US Highway 322, then over US Highway 322 to junction PA Highway 3, then over PA Highway 3 to Philadelphia, and return over the same route. (B) From Big Run over US Highway 119 to junction US Highway 422, then over US Highway 422 to junction US Highway 22, then over US Highway 22 to junction Interstate Highway 83, then over Interstate Highway 83 to junction PA Highway 283, then over PA Highway 283 to junction US Highway 30, then over US Highway 30 to Philadelphia, and return over the same route. (II) Between Big Run, Jefferson County, PA, and Pittsburgh, PA, serving points within 25 miles of Big Run, PA, as intermediate and/or off-route points, and points in Elk, Potter, Tioga, and Cameron Counties, PA, as off-route points and serving the intermediate point of Indiana, PA, and Kittanning, PA. (A) From Big Run over US Highway 119 to junction US Highway 22, then over US Highway 22 to Pittsburgh, and return over the same route. (B) From Big Run over US Highway 119 to junction Pennsylvania Highway 210, then over Pennsylvania Highway 210 to junction Pennsylvania Highway 85, then over Pennsylvania Highway 85 to junction Pennsylvania Highway 28, then over Pennsylvania Highway 28 to Pittsburgh, and return over the same route. (C) From Big Run over US Highway 119 to junction US Highway 422, then over US Highway 422 to junction Pennsylvania Highway 8, then over Pennsylvania Highway 8 to Pittsburgh, and return over the same route. (III) Between Bradford, PA, and Pittsburgh, PA, serving points in Elk, Potter, Tioga, and Cameron Counties, PA, and those within 30 miles of Bradford, PA, as intermediate and/or off-route points, and serving intermediate points located at and between Rolfe and Elbon, PA, and serving the intermediate point of Kittanning, PA. (A) From Bradford over US Highway 219 to junction US Highway 22, then over US Highway 22 to Pittsburgh, and return over the same route. (B) From Bradford over US Highway 219 to junction US Highway 6, then over US Highway 6 to junction PA Highway 66, then over PA Highway 66 to junction US Highway 322, then over US Highway 322 to junction PA Highway 68, then over PA Highway 68 to junction PA Highway 8, then over PA Highway 8 to Pittsburgh, and return over the same route. (C) From Bradford over US Highway 219 to junction PA Highway 28, then over PA Highway 28 to Pittsburgh, and return over the same route.

(D) From Bradford over US Highway 219 to junction PA Highway 770, then over PA Highway 770 to junction PA Highway 59, then over PA Highway 59 to junction US Highway 6, then over US Highway 6 to junction US Highway 62, then over US Highway 62 to junction PA Highway 8, then over PA Highway 8 to Pittsburgh, and return over the same route. (IV) Between Bradford, PA, and Philadelphia, PA, serving those intermediate points between Bradford

and Clearfield, PA, and points in Elk, Potter, Tioga, and Cameron Counties, PA, and points within 25 miles of Big Run, PA, as off-route points: (A) From Bradford over US Highway 219 to junction PA Highway 255, then over PA Highway 255 to junction PA Highway 153, then over PA Highway 153 to junction US Highway 322, then over US Highway 322 to junction US Highway 422, then over US Highway 422 to Philadelphia, and return over the same route. (B) From Bradford over US Highway 219 to junction PA Highway 255, then over PA Highway 255 to junction Interstate Highway 80, then over Interstate Highway 80 to junction PA Highway 309, then over PA Highway 309 to Philadelphia, and return over the same route. (C) From Bradford to junction Interstate Highway 80 as in IV. (A), above, then over Interstate Highway 80 to junction PA Highway 9, then over PA Highway 9 to junction US Highway 422, then over US Highway 422 to Philadelphia, and return over the same route. Restrictions: The authority granted herein is subject to the following conditions: As to Parts II. A and II. C, above, service at Indiana, PA, is restricted to traffic originating at or destined to, points in New York State, except New York, NY, and those in Nassau, Rockland, Suffolk, and Westchester Counties, NY. Carrier shall not, pursuant to the irregular-route authority granted in MC-109821 (Sub-No. 40), transport shipments moving between any points authorized to be served by it in the operations authorized by this certificate. Any repetition in the statement of the authority granted herein with any other authority held by Taynton Freight System, Inc., shall not be construed as conferring more than one operating right, and shall not be severable by sale or otherwise.

MC-109821 Sub 66 authorizes transportation, over regular routes, of *general commodities* (except household goods as defined by the Commission, Classes A and B explosives, commodities in bulk, commodities requiring special equipment, and those of unusual value), between Norristown, PA, and Washington, DC, serving all intermediate points, and off-route points within 10 miles of Norristown, from Norristown over U.S. 202 to junction U.S. Hwy 30, at or near Paoli, PA, thence over U.S Hwy 30 to Coatesville, PA, thence over Pennsylvania Hwy 82 to junction unnumbered hwy (formerly Pennsylvania Hwy 182), thence over unnumbered hwy to junction Pennsylvania Hwy 10 at or near Coachranville, PA, thence over Pennsylvania Hwy 10 to Oxford, PA., thence over U.S. Hwy 1 to junction unnumbered highway (formerly U.S. Hwy 1), thence over unnumbered highway to the Pennsylvania-Maryland State line, thence continue over unnumbered highway to junction Maryland Hwy 273, thence over Maryland Hwy 273 to junction U.S. Hwy 1, thence over U.S. Hwy 1 to Washington, DC, and return over the same route, restricted against local service on U.S. Hwy 1 between Baltimore, MD and Washington, DC., including the named points. By the instant petition, petitioner seeks to consolidate the above authorities to read as follows: *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk and those requiring special equipment), between points in DE, NY, PA, and DC, and those points in MD, VA and WV on and north of U.S. Hwy 50, serving all intermediate and off-route points over the following specified routes: (1) between Parkersburg, WV, and Ocean City, MD, over U.S. Hwy 50, and return over the same route, (2) between Wheeling, WV, and Manor Park, DE, over U.S. Hwy 40, and return over the same route, (3) between Chester, WV, and Frazer PA, over U.S. Hwy 30 and return over the same route, (4) betwen Weirton, WV, and Easton, PA, over U.S. Hwy 22, and return over the same route, (5) between West Springfield, PA, and Bridgewater, NY, Over U.S. Hwy 20, and return over the same route, (6) between Westfield, NY, and Suffern, NY, Over NY Hwy 17, and return over the same route, (7) between Pennline, PA, and Matamoras, PA, over U.S. Highway 6, and return over the same route, (8) between Toll Gate Number 1 and Toll Gate Number 29 of the Pennsylvania Turnpike, over the Pennsylvania Turnpike, and return over the same route, (9) between Parkersburg, WV, and Chester, WV, over WV Hwy 2, and return over the same route, (10) between Jamestown, PA and Chester, PA, over U.S. Hwy 322, and return over the same route, (between Frederick, MD, and Washington, DC, over Interstate Hwy 270, and return over the same route, (12) between Alexandria, VA, and Chester, PA, over Interstate Hwy 95, and return over the same route, (13) between West Middlesex, PA., and Delaware Water Gap, PA, over Interstate Hwy 80, and return over the same route, (14) between Washington, PA, and Baltimore, MD, over Interstate Hwy 70, and return over the same route, (15) between Salisbury, MD, and Bristol, PA, over U.S. Hwy 13, and return over the same route, (16) between Gilberts Corners, VA, and Painted Post, NY, over U.S. Hwy 15, and return over the same route, (17) between Clarksburg, WV, and Erie, PA, over U.S. Hwy 19, and return over the same route, (18) between Bridgeport, WV, and Erie, PA, over Interstate Hwy 79, and return over the same route, (19) between Kernstown, Va, and Pulaski, NY, over Interstate Hwy 81 (also U.S. Hwy 11), and return over the same route, (2) between Baltimore, MD, and Harrisburg, PA, over Interstate Hwy 83, and return over the same route, (21) between Grafton, WV, and Sandy, PA, over U.S. Hwy 119, and return over the same route, (22) between Redhouse, MD, and North Boston, NY, over U.S. Hwy 219, and return over the same route, (23) between New Creek, VA, and South Waverly, PA, over U.S. Hwy 220, and return over the same route, and (24) between Morgantown, WV, and Cumberland, MD, over U.S. Hwy 48, and return over the same route.

Republications of Grants of Operating Rights; Authority Prior to Certification Notice

The following grants of operating rights authorities are republished by order of the Commission to indicate a broadened grant of authority over that previously noticed in the Federal Register.

An original and one copy of a petition for leave to intervene in the proceeding must be filed with the Commission within 30 days after the date of this Federal Register notice. Such pleading shall comply with Special Rule 247(e) of the Commission's *General Rules of Practice* (49 CFR 1100.247) addressing specifically the issue(s) indicated as the purpose for republication, and including copies of intervenor's conflicting authorities and a concise statement of intervenor's interest in the proceeding setting forth in detail the precise manner in which it has been prejudiced by lack of notice of the authority granted. A copy of the pleading shall be served concurrently upon the carrier's representative, or carrier if no representative is named.

MC 19311 (Sub-59F) (Republication), filed March 30, 1979, previously noticed in the Federal Register issue of August 28, 1979. Applicant: CENTRAL TRANSPORT, INC., 34200 Mound Road, Sterling Heights, MI 48077. Representative: Elmer J. Maue, 755 West Big Beaver Rd., Suite 1200, Troy, MI 48084. An Initial Decision by the Commission, Administrative Law Judge, decided April 18, 1980, and served April 30, 1980, finds that the public convenience and necessity require

operation by applicant, in interstate or foreign commerce, to operate as a *common carrier,* by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *voting machines,* from Jamestown, NY, to points in IL, IN, MI, OH and WI, and (2) *new furniture, new household office and store fixtures, and furnishings,* (a) from points in IL, IN, OH, and WI, to points in CT, ME, MD, MA, NH, NJ, NY, PA, RI, and VT, and (b) from points in MA, NH, NJ, NY, PA, and NH, to points in IL, IN, OH, and WI. Applicant is fit, willing, and able properly to perform such service and to conform to the requirements of Title 99, Subtitle IV, US Code, and the Commission's regulations. The purpose of this republication is to add the destination states of MI and WI in part (1) above.

MC 115331 (Sub-489F) (Republication), filed March 16, 1979, previously noticed in the Federal Register issue of July 18, 1979. Applicant: TRUCK TRANSPORT INCORPORATED, 29 Clayton Hills Lane, St. Louis, MO 63131. Representative: J. R. Ferris, 230 St. Clair Avenue, East St. Louis, IL 62201. A Decision by the Commission, Review Board Number 1, decided April 2, 1980, and served April 8, 1980, finds that the present and future public convenience and necessity require operation by applicant, as a *common carrier,* by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *cement* from the facilities of The Marquette Company, at Cape Girardeau, MO, to points in AR, IL, IN, KY, MS, OK, and TN and (2) *materials and supplies used in the production of cement,* in the reverse direction. Applicant is fit, willing, and able properly to perform the granted service and to conform to the requirements of Title 49, Subtitle IV, U.S. Code, and the Commission's regulations. The purpose of this republication is that Kentucky was omitted in the territorial description.

MC 129291 (Sub-10F) (republication), filed November 8, 1978, previously noticed in the FR issue of February 23, 1979. Applicant: McDANIEL MOTOR EXPRESS, INC., 1115 Winchester Road, Lexington, KY 40505. Representative: George M. Catlett, 708 McClure Building, Frankfort, KY 40601. By the Commission, Review Board Number 2, decided March 13, 1980, and served April 15, 1980, finds that the present and future public convenience and necessity require operation by applicant, as a *common carrier,* by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Paris and Carlisle, KY, from Paris over U.S. Hwy 68 to the southernmost junction of U.S. Hwy 68 and KY Hwy 32, then over KY Hwy 32 to Carlisle, and return over the same route, serving all intermediate points, restricted against the transportation of traffic originating at, or destined to the facilities of W. R. Stamler Corp., at or near Millersburg, KY. Applicant is fit, willing, and able properly to perform the granted service and to conform to the requirements of Title 49, Subtitle IV, U.S. Code, and the Commission's regulations. The purpose of this republication is to show the actual authority granted.

MC 148151F, filed August 17, 1979, previously noticed in the Federal Register of February 26, 1980. Applicant: RAY BALLEW & SONS, INC., 7810 Almeda-Genoa Road, Houston, TX 77075. Representative: John W. Carlisle, 6746 De Moss, Suite 194, Houston, TX 77074. Transporting *general commodities,* (except classes A & B explosives) between points in the Commercial Zones of Houston, Galveston, Texas City, Baytown, Beaumont, Port Arthur, Orange, La Porte, Port Lavaca, Corpus Christi, Bay City, Port O'Connor, Brownsville, and Port of Brownsville, TX, and New Orleans Baton Rouge and Lake Charles, LA, restricted to the transportation of traffic having a prior or subsequent movement by water. This application was inadvertently published with those applications governed by Special Rule 247 of the Commission's Rules of Practice (49 CFR § 1100.247). The application was filed under Ex Parte MC 105 and should have appeared in the Federal Register with those applications governed by (49 CFR 1062.3). The purpose of this republication is to publish this application under the proper rules. NOTE: No action will be taken on petitions filed pursuant to the February 26 publication. (Hearing site: Houston, TX.)

Permanent Authority Decisions Volume; Decision-Notice

Decided: May 9, 1980.

The following broker, freight forwarder or water carrier applications are governed by Special Rule 247 of the Commission's *Rules of Practice* (49 CFR § 1100.247). These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission on or before June 26, 1980. Failure to file a protest within 30 days will be considered as a waiver of opposition to the application. A protest under these rules shall comply with Rule 247(e)(3) of the Rules of Practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding, as specifically noted below), and specify with particularity the facts, matters, and things relied upon. The protest shall not include issues or allegations phrased generally. A protestant shall include a copy of the specific portion of its authority which it believes to be in conflict with that sought in the application, and describe in detail the method—whether by joinder, interline, or other means—by which protestant would use this authority to provide all or part of the service proposed. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission. A copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named. If the protest includes a request for oral hearing, the request shall meet the requirements of section 247(e)(4) of the special rules and shall include the certification required in that section.

Section 247(f) provides, in part, that an applicant which does not intend timely to prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exceptions of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each applicant has demonstrated that its proposed service is either (a) required by the public convenience and necessity, or, (b) will be consistent with the public interest and the transportation policy of 49 U.S.C. § 10101. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the

requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision notice. To the extent that the authority sought below may duplicate an applicant's existing authority, such duplication shall not be construed as conferring more than a single operating right.

Applicants must comply with all specific conditions set forth in the grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 1, Members Carlton, Joyce, and Jones.

MC 12169 (Sub-1F), filed April 14, 1980. Applicant: S & C CORP., d.b.a. PIEDMONT TOURS, 6 River Street, Piedmont, SC 29673. Representative: Maxwell A. Howell, 1100 Investment Building, 1511 K Street, NW., Washington, DC 20005. To engage in operations in interstate or foreign commerce, as a *broker* at Piedmont, SC, in arranging for the transportation, by motor vehicle, of *passengers and their baggage,* in special and charter operations, between points in the U.S. (including AK and HI). (Hearing site: Greenville, SC.)

MC 130159 (Sub-1F), filed March 13, 1980. Applicant: LOUISVILLE AUTOMOBILE CLUB, a corporation, 435 East Broadway, Louisville, KY, 40202. Representative: William Kiel, 1205 Kentucky Home Life Building, Louisville, KY 40202. To engage in operations, in interstate or foreign commerce, as a *broker* at Louisville, Bowling Green, Elizabethtown, Owensboro, Paducah, and Frankfort, KY, in arranging for the transportation by motor vehicles of *passengers and their baggage,* in special and charter operations, between points in the U.S. (including AK and HI). (Hearing site: Louisville or Frankfort, KY.)

MC 130799F, filed March 4, 1980. Applicant: TRAVEL ASSOCIATES, INC. OF STATESVILLE, P.O. Box 1697, Signal Hill Mall, Statesville, NC 28677. Representative: Dorothy J. Pendleton (Same address as applicant). To engage in operations, in interstate or foreign commerce, as a *broker* at Statesville, NC, in arranging for the transportation by motor vehible, of *passengers and their baggage,* in special and charter operations, between Statesville, NC, on the one hand, and, on the other, points in the U.S. (including AK and HI). (Hearing site: Statesville or Winston-Salem, NC.)

MC 130804F, filed March 4, 1980. Applicant's name and address are ADVANCED TRANSPORTATION SERVICES COMPANY, INC., (a.k.a. ATSCO), 3022 Number Hesperian, Santa Ana, CA 92706. The name under which operations will be performed is ATSCO. Applicant is represented by Robert J. Gallagher, in this proceeding, whose address is suite 1200, 1000 Connecticut Avenue, N.W., Washington, DC 20036. Following are the names and business addresses for all persons who are officers and directors, partners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles: A. E. Huntington, President, Director, and shareholder, Robert E. Scott, Executive Vice President, Director, and shareholder, Thomas A. Paxton, Vice President of Operations, Director, and shareholder, and June C. Huntington, Secretary, Treasurer, Director, and shareholder, (same address as applicant). The daily operations will be managed by Robert E. Scott, whose business address is 3022 No. Hesperian, Santa Ana, CA 92706. Applicant is affiliated with the following shipper or warehouse: None.

MC 130805F, filed March 6, 1980. Applicant's name and address are COLLINS MOVING SYSTEMS, INC., 904 West Morgan Street, Kokomo, IN 46901. The name under which operations will be performed is COLLINS MOVING SYSTEMS, INC. Applicant is represented by Robert J. Gallagher, in this proceeding, whose address is suite 1200, 1000 Connecticut Avenue, NW, Washington, DC 20036. Following are the names and business addresses for all persons who are officers an directors, parners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles: Harold A. Collin, President and Director/Shareholder, and Dathel L. Collins, Secretary & Director/ Shareholder whose addresses are the same as the applicant. The daily operations will be managed by Harold A. Collins, whose address is the same as the applicant. Applicant is affiliated with the following shipper or warehouse: None.

MC 130806F, filed March 13, 1980. Applicant: UNIQUE TOURS, 98 Lewis Avenue, Meriden, CT 06450. Representative: Pino Parisi (same address as applicant). To engage in operations, in interstate or foreign commerce, as a *broker* at Meriden, CT, in arranging for the transportation of *passengers and their baggage,* between Meriden, CT, on the one hand, and, on the other, points in the U.S. (including AK and HI) (hearing site: New Haven, CT.)

MC 130816F, filed February 28, 1980. Applicant's name and address are NORTH CENTRAL DISPATCH, INC., 1515 Oak Road, Eagan, MN 55121. The name under which operations will be performed is NORTH CENTRAL DISPATCH, INC. Applicant is represented by Robert L. Cope in this proceeding, whose address is suite 501, 1730 M Street, N.W., Washington, DC 20036. Following are the names and business address for all persons who are officers and directors, partners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles: Donald B. Taylor, President, Treasurer and shareholder, Suzanne Taylor, Vice President and shareholder, both addresses same as applicant, and Harry Strong, Secretary, 201 Security Bldg. St. Paul, MN 55114. The daily operations will be managed by Donald B. Taylor whose business address is 1515 Lone Oak Rd., Eagan, MN 55121. Applicant is affiliated with the following shipper or warehouse: None.

MC 130817F, filed March 14, 1980. Applicant's name and address are P. H. PETRY CO., 53 Park Place, New York, NY 10007. The name under which operations will be performed is P. H. PETRY CO. Applicant is represented by H. Klestadt in this proceeding, whose address is 53 Park Place, New York, NY 10007. Following are the names and business address for all persons who are officers and directors, partners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles: Harry A. Stern, President, Director, and shareholder, Lothar Klestadt, Vice President, Director, and shareholder, and Helmut Klestadt, Secretary, Director, and shareholder, all addreses same as applicant. The daily operations will be managed by Lothar Klestadt, whose business address is 53 Park Place, New York, NY 10007. Applicant is affiliated with the following shipper or warehouse: None.

MC 130821F, filed March 26, 1980. Applicant: AAA WORLD TRAVEL OF CORNHUSKER MOTOR CLUB, INC., 5011 Capitol Avenue, Omaha, NE 68103. Representative: Lawrence E. Lindeman, suite 1032, 425 13th Street, N.W., Washington, DC 20004. To engage in operations, in interstate or foreign commerce, as a *broker* at Omaha, Lincoln, Grand Island, Norfolk, North Platte, and Scottsbluff, NE, in arranging for the transportation by motor vehicle of *passengers and their baggage,* in special and charter operations, between points in the United States (including AK but excluding HI). (Hearing site: Omaha, NE.)

MC 130826F, filed February 28, 1980. Applicant's name and address are BAILEY FOREIGN FREIGHT FORWARDING, INC., 1932 Lebanon St., Hyattsville, MD 20783. The name under which operations will be performed is BAILEY FOREIGN FREIGHT FORWARDING, INC. Applicant is represented by Charles L. Clow in this proceeding, whose address is 815 Bowen Bldg., Suite 525A, Washington, DC 20005. Following are the names and business addresses for all persons who are officers and directors, partners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles: Frank R. Bailey, president and shareholder, and Sue Bailey, vice president and shareholder, both addresses same as applicant. The daily operations will be managed by Frank R. Bailey whose business address is 1932 Lebanon St., Hyattsville, MD 20783. Applicant is affiliated with the following shipper or warehouse: None.

MC 130828F, filed March 27, 1980. Applicant's name and address are James A. Andrulis, W221 S1140 Cherokee Dr., Waukesha, WI 53186. The name under which operations will be performed is ANDRULIS & ASSOCIATES. Applicant is represented by itself in this proceeding whose address is same as above. Following are the names and business addresses for all persons who are officers and directors, partners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles; James A. Andrulis, Sole Proprietor, W221 S1140 Cherokee Dr., Waukesha, WI 53186. The daily operations will be managed by James A. Andrulis whose address is same as applicant's. Applicant is affiliated with the following shipper or warehouse: None.

MC 130839F, filed April 1, 1980. Applicant AMERICAN ADVENTURE TRAVEL, INC., 413 South President Street, Jackson, MS 39201. Representative: Suzanne H. Pugh (same address as applicant). To engage in operations, in interstate or foreign commerce, as a *broker* at Jackson, MS, in arranging for the transportation by motor vehicle, of *passengers and their baggage,* in special or charter operations, between points in Hinds County, MS, on the one hand, and, on the other, points in the US (including AK and HI). (Hearing site: Jackson, MS.)

MC 130846F, filed April 3, 1980. Applicant's name and address are S & M TRANSFER & STORAGE COMPANY, a California corporation, 1916 Border Ave., Torrance, CA 90501. The name under which operations will be performed is S & M TRANSFER & STORAGE COMPANY. Applicant is represented by John C. Russell, in this proceeding whose address is 1545 Wilshire Blvd., Los Angeles, CA 90017. Following are the names and business addresses for all persons who are officers and directors, partners (including limited or "silent" partners), and first five principal shareholders, with their appropriate titles: G. W. Stadler, President, Director, Shareholder, G. P. Stadler, Vice President, Director, and Shareholder, and C. V. Stadler, Secretary, Director, and Shareholder, whose addresses are the same as applicant's. The daily operations will be managed by G. P. Stadler, whose business address is 1916 Border Ave., Torrance, CA 90501. Applicant is affiliated with the following shipper or warehouse: None.

MC 130852F, filed April 9, 1980. Applicant: CHALET TRAVEL SERVICE, INC., 2824 Country Club Drive, West, Oklahoma City, OK 73116. Representative: Fred A. Hahn (same address as applicant). To engage in operations, in interstate or foreign commerce, as a *broker,* at Oklahoma City, OK, in arranging for the transportation, by motor vehicle, of *passengers and their baggage,* in special or charter operations, between points in OK, on the one hand, and, on the other, points in the U.S. (except AK and HI). (Hearing site: Oklahoma City or Tulsa, OK.)

MC 130873, filed April 3, 1980. Applicant's name and address are MITCHELL INTERNATIONAL ENTERPRISES, 18800 Southcenter Parkway, Seattle, WA 98188. The name under which operations will be performed is MITCHELL INTERNATIONAL ENTERPRISES, INC. Applicant is represented by itself at the above address. Following are the names and business addresses for all persons who are officers and directors, partners (including limited or "silent" partners), and principle shareholders (there are only two shareholders), and their addresses: Hugh B. Mitchell, President and Chairman of the Board, Mitchell International Enterprises (same address as applicant). Mr. Mitchell is a principle shareholder. Walter Griffin, Member, Board of Directors, 5156 48th NE, Seattle, WA 98105. George O. Lane, Board of Directors, 7 Highland Dr, Seattle, WA, 98109. Bruce C. Mitchell, Vice-President, Mitchell International Enterprises (same address as applicant). Ted Griebling, Shareholder, 12025 Standring Court SW, Seattle, WA, 98146. John Wheeler, Secretary and General Manager, Mitchell International Enterprises (same address as applicant). The daily operations will be managed by John Wheeler, whose business address is (same as applicant). Applicant is affiliated with the following shipper or warehouse: None.

Permanent Ex-Water Authority Decision-Notices

Decided: May 9, 1980.

The following applications are governed by 49 CFR 1062.3. Applicants seek to obtain motor common carrier authority to perform service within the commercial zone of port cities where the shipment has a prior or subsequent movement by maritime carrier. The full text and explanation of the rules are contained at 44 FR 7965, as corrected at 44 FR 37230.

The sole issue upon which these applications can be protested is the applicant's fitness to perform the service. Protests (an original and one copy) must be filed with the Commission within 30 days of the Federal Register publication. The protest must contain the *specific facts* being relied upon to challenge fitness, and must contain a certification that it has been served concurrently upon applicant's representative, or, if none is listed, upon the applicant. Applicant may file a reply statement to any protest. The filing of these statements will complete the record, unless it is later determined that more evidence must be supplied.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.gs., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the present and future public convenience and necessity.

Each applicant is fit, willing, and able to properly perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In those proceedings containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a protestant, that the proposed dual operations are consistent with the public interest and the transportation policy of 49 U.S.C. 10101 subject to the right of the Commission, which is expressly reserved, to impose such terms, conditions or limitations as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. 10930(a) (formerly section 210 of the Interstate Commerce Act).

In the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of the decision-notice. To the extent that the authority sought below may duplicate an applicant's other authority, such duplication shall be construed as conferring only a single operating right.

Applicants must comply with all specific conditions set forth in the grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 1, Members Carlton, Joyce, and Jones.

MC 150373F, filed March 19, 1980. Applicant: GUY H. DONALD, JR., d.b.a. CONTAINER TRANSPORT CO., 3410 Edgewood Ave., Jacksonville, FL 32205. Representative Sol H. Proctor, 1101 Blackstone Bldg., Jacksonville, FL 32202. Transporting *general commodities* (except classes A and B explosives), between points in the commercial zone of Jacksonville, FL, restricted to traffic having a prior or subsequent movement by water. (Hearing site: Jacksonville, FL.)

Permanent Authority Notces
Substitution Applications: Single-line Service for Existing Joint-Line Service

The following applications, filed on or after April 1, 1979, are governed by the special procedures set forth in Part 1062.2 of Title 49 of the Code of Federal Regulations (49 CFR 1062.2). These proposals are published as "service sought", (as opposed to decision-notices), because in each case it appears questionable as to whether all or part of the authority sought should be issued, weighing applicant's evidence under 49 CFR 1062.2. (For example, questions may be raised relating to applicant's contentions concerning why the involved joint-line service has been cancelled or is in a state of deterioration which warrant a decision on the merits, regardless of whether the application is opposed.)

The rules provide, in part, that carriers may file petitions with this Commission for the purpose of seeking intervention in these proceedings. Such petitions may seek intervention either with or without leave as discussed below. However, all such petitions must be filed in the form of verified statements, and contain all of the information offered by the submitting party in opposition. Petitions must be filed with the Commission within 30 days of publication of this decision-notice.

Petitions for intervention without leave (i.e., automatic intervention), may be filed only by carriers which are, or have been, participating in the joint-line service sought to be replaced by applicant's single-line proposal, and then only if such participation has occurred within the one-year period immediately preceding the application's filing. Only carriers which fall within this filing category can base their opposition upon the issue of the public need for the proposed service.

Petitions for intervention with leave may be filed by any carrier. The nature of the opposition, however, must be limited to issues other than the public need for the proposed service. The appropriate basis for opposition, i.e., applicant's fitness, may include challenges concerning the veracity of the applicant's supporting information, and the bona-fides of the joint-line service sought to be replaced (including the issue of its substantiality). Petitions containing only unsupported and undocumented allegations will be rejected.

Petitions not in reasonable compliance with the requirements of the rules may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

MC 42828 (Sub-20F), filed February 26, 1980. Applicant: THEODORE ROSSI TRUCKING CO., INC., 9 South Vine Street, Barre, VT 05641. Representative: William L. Rossi, P.O. Box 332, Barre, VT 05641. Authority sought to operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *stone*, from Barre, Northfield, South Ryegate, Morrisville, and Groton, VT, to those points in the United States in an east of WI, IL, MO, OK, and TX. (Hearing site: Barre, VT.)

Note.—The sole purpose of this application is to substitute single-line for joint-line operations.

Permanent Authority Decisions; Decision-Notice Substitution Applications: Single-Line Service for Existing Joint-Line Service

Decided: May 8, 1980.

The following applications, filed on or after April 1, 1979, are governed by the special procedures set forth in Part 1062.2 of Title 49 of the Code of Federal Regulations (49 CFR 1062.2).

The rules provide, in part, that carriers may file petitions with this Commission for the purpose of seeking intervention in these proceedings. Such petitions may seek intervention either with or without leave as discussed below. However, all such petitions must be filed in the form of verified statements, and contain all of the information offered by the submitting party in opposition. Petitions must be filed with the Commission within 30 days of publication of this decision-notice.

Petitions for intervention without leave (i.e. automatic intervention), may be filed only by carriers which are, or have been, participating in the joint-line service sought to be replaced by applicant's single-line proposal, and then only if such participation has occurred within the one-year period

immediately proceeding the application's filing. Only carriers which fall within this filing category can base their opposition upon the issue of the public need for the proposed service.

Petitions for intervention with leave may be filed by any carrier. The nature of the opposition; however, must be limited to issues other than the public need for the proposal service. The appropriate basis for opposition, i.e. applicant's fitness, may include challenges concerning the veracity of the applicant's supporting information, and the bona-fides of the joint-line service sought to be replaced (including the issue of its substantiality). Petitions containing only unsupported and undocumented allegations will be rejected.

Petitions not in reasonable compliance with the requirements of the rules may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

Further processing steps will be by Commission notice, decision, or letter will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.gs., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each applicant has demonstrated that its proposed service is required by the present and future public convenience and necessity. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In thos proceedings containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a petitioner, that the proposed dual operations are consistent with the public interest and the transportation policy of 49 U.S.C. 10101 subject to the right of the Commission, which is expressly reserved, to impose such terms, conditions or limitations as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. 10930(a) (formerly section 210 of the Interstate Commerce Act).

In the absence of legally sufficient petitions for intervention, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of the decision-notice. To the extent that the authority sought below may duplicate an applicant's other authority, such duplication shall be construed as conferring only a single operating right.

Applicants must comply with all specific conditions set forth in the grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 4, Members Fitzpatrick, Fisher, and Dowell.

MC 35334 (Sub-85F), filed January 22, 1980. Applicant: COOPER-JARRETT, INC., Hanover Plaza, Morristown, NJ 07960. Representative: Irving Klein, 371 Seventh Avenue, New York, NY 10001. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Rockford, IL, and Milwaukee, WI, on the one hand, and, on the other, points in WI. (Hearing site: New York, NY, or Washington, DC.)

Note.—Applicant intends to tack the authority sought with its existing authority. The sole purpose of this application is to substitute single-line for joint-line operations.

MC 60430 (Sub-30F), filed November 16, 1979. Applicant: FRIEDMAN'S EXPRESS, INC., P.O. Box 480, Wilkes-Barre, PA 18703. Representative: Maxwell A. Howell, 1100 Investment Building, 1511 K Street, N.W., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Allentown, Bloomsburg, Easton, Reading and Scranton, PA, on the one hand, and, on the other, Camp Hill, Mechanicsburg, and Gettysburg, PA, and points in PA on and east of US Hwy 15. (Hearing site: Washington, DC.)

Note.—The purpose of this application is to substitute single-line for joint-line operations. Applicant intends to tack with its existing authority.

MC 69281 (Sub-51F), filed April 10, 1979. Applicant: THE DAVIDSON TRANSFER & STORAGE CO., a corporation, 698 Fairmount, Avenue Towson, MD 21204. Respresentative: Henry J. Bouchat, P.O. Box 58, Baltimore, MD 21203. Authority sought to transport as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by Commission, commodities in bulk, and those requiring special equipment), (1) between Harrisbury, PA, and Indianapolis, IN, from Harrisburg over Interstate Hwy 76 to junction Interstate Hwy 70, then over Interstate Hwy 70 to Indianapolis, and return over the same route, (2) between Jersey City, NJ, and Harrisburg, PA, from Jersey City over U.S. Hwy 1 to junction Interstate Hwy 78, then over Interstate Hwy 78 to Harrisburg, PA, and return over the same route, (3) between Jersey City, NJ, and Chicago, IL, from Jersey City over U.S. Hwy 1 to junction Interstate Hwy 280, then over Interstate Hwy 280 to junction Interstate Hwy 80, then over Interstate Hwy 80 to junction Interstate Hwy 90, then over Interstate Hwy 90 to Chicago, and return over the same route, (4) between Baltimore, MD, and Indianapolis, IN, over Interstate Hwy 70, (5) between Baltimore, MD, and Chicago, IL, from Baltimore over Interstate Hwy 70 to junction Interstate Hwy 76, then over Interstate Hwy 76 to junction Interstate Hwy 80, then over Interstate Hwy 80 to junction Interstate Hwy 90, then over Interstate Hwy 90 to Chicago, and return over the same route, (6) between Indianapolis, IN, and junction Interstate Hwys 65 and 90 at or near Gary, IN, over Interstate Hwy 65, (7) between Indianapolis, IN, and St. Louis, MO, from Indianapolis over Interstate Hwy 70 to junction Interstate Hwy 55, then over Interstate Hwy 55 to St. Louis, and return over the same route, serving points in IA, IL, IN, KS, KY, MI, MN, MO, OH, OK, TX, and WI, as intermediate and off-route points.(Hearing site: Washington, DC.)

Note.—Applicant intends to tack with existing authority at Baltimore, MD, Jersey City, NJ, and Harrisburg, PA. The purpose of this application is to substitute single-line for joint-line operations.

MC 115092 (Sub-104F), filed January 10, 1980. Applicant: THOMAHAWK TRUCKING, INC., P.O. Box 0, Vernal, UT 84078. Respresentative: Walter Kobos, 1016 Kehoe Drive, St. Charles, IL 60174. To operate as a *common carrier*, by motor vehicle, in interestate or foreign commerce, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses, as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Cettificates, 61 M.C.C. 209 and 766* (except hides and commodities in bulk), and *canned goods* from Boulder, Brighton, Denver, Englewood, Fort Morgan, Loveland and Sterling, CO to points in AZ and CA. The sole purpose of this application is to substitute single line for joint-line operations. (Hearing site: Salt Lake City, UT.)

MC 138322 (Sub-21F), filed February 5, 1980. Applicant: BHY TRUCKING, INC., 9231 Whitmore Street, El Monte, CA 91733. Representative: Robert Fuller, 13215 East Penn Street, Suite 310, Whittier, CA 90602. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except those of unusual value, automobiles, liquors, cigarettes, cotton, lumber, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, those requiring refrigeration or tank truck equipment, and commodities dealt in by grocery and department stores), between Los Angeles and El Monte, CA, on the one hand, and, on the other, points in AZ, CA and TX. (Hearing site: Los Angeles, CA.)

Note.—The sole purpose of this application is to substitute singleline for joint-line operations. Applicant intends to tack the authority sought with its existing authority.

Irregular-Route Motor Common Carriers of Property; Elimination of Gateway Applications

The following applications to eliminate gateways for the purpose of reducing highway congestion, alleviating air and noise pollution, minimizing safety hazards, and conserving fuel have been filed with the Interstate Commerce Commission under the Commission's Gateway Elimination Rules (49 CFR 1065(d)(2)) and notice thereof to all interested persons is hereby given as provided in such rules.

Carriers having a genuine interest in an application may file an original and three copies of verified statements in opposition with the Interstate Commerce Commission on or before *30 days from publication.* (This procedure is outlined in the Commission's report and order in Gateway Elimination, 119 M.C.C. 530). A copy of the verified statement in opposition must also be served upon applicant or its named representative. The verified statement should contain all the evidence upon which protestant relies in the application proceeding including a detailed statement of protestant's interest in the proposal. No rebuttal statements will be accepted.

MC 113666 (Sub-97G), filed December 31, 1979, and previously noticed in the Federal Register issue of April 15, 1980. Applicant: FREEPORT TRANSPORT, INC., 1200 Butler Road, Freeport, PA 16229. Representative: William H. Shawn, 1730 M Street NW., suite 501, Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, in interstate or foriegn commerce, over irregular routes, transporting *refractory products* (except in bulk), (1) from points in PA, to points in NY, MI, IL, IN, OH, MD, NJ, and WV, (2) from points in OH, to points in IN, IL, OH, NY, NJ, MI, PA, and MD, (3) from points in KY, to points in PA, IL, IN, OH, MD, WV, NJ, MI, and NY, (4) from points in MO, to points in MI, WV, OH, IL, and IN, and (5) from points in WV, to points in NY, MI, NJ, IL, IN, OH, MD, and PA, restricted against the transportation (1) of refractory products from Clearfield, PA, and points within 25 miles thereof, and from Clymer, Mt. Union, and Womelsdorf, PA; (2) of materials and supplies used in the installation of refractory products when transported in mixed shipments with refractory products from Clearfield, PA, and points within 25 miles thereof, and from Mt. Union and Womelsdorf, PA; and (3) of brick, structural tile, and crude clay (in bulk), from Clearfield, PA, and points within 25 miles thereof. The purpose of this filing is to eliminate the gateways of Detroit, MI and Buffalo, NY. (Hearing site: Washington, DC.)

Note.—This republication is to include the above restriction which was previously omitted and to correct the territorial description in part (3) of this proceeding.

Irregular-Route Motor Common Carriers of Property; Elimination of Gateway Letter Notices

The following letter-notices of proposals to eliminate gateways for the purpose of reducing highway congestion, alleviating air and noise pollution, minimizing safety hazards, and conserving fuel have been filed with the Interstate Commerce Commission under the Commission's *Gateway Elimination Rules* (49 CFR 1065), and notice thereof to all interested persons is hereby given as provided in such rules.

An original and two copies of protests against the proposed elimination of any gateway herein described may be filed with the Interstate Commerce Commission on or before June 6, 1980. A copy must also be served upon applicant or its representative. Protests against the elimination of a gateway will *not* operate to stay commencement of the proposed operation.

Successively filed letter-notices of the same carrier under these rules will be numbered consecutively for convenience in identification. Protests, if any, must refer to such letter-notices by number.

The following applicants seek to operate as a *common carrier*, by motor vehicles, over irregular routes.

MC 124211 (Sub-F102), filed August 22, 1977. Applicant: HILT TRUCK LINE, INC., P.O. Box 988, D.T.S., Omaha, NE 68101. Representative: Thomas L. Hilt (same address as applicant). *Meats, meat products, meat byproducts, and articles distributed by meat packinghouses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), (a) from points in NE on, south and east of a line beginning at the IA–NE State line, thence over US Hwy 30 to junction NE Hwy 15, thence over NE Hwy 15 to the KS–NE State line (except from points in Douglas and Washington Counties, NE), to points in Clay and Union Counties, SD (Points in Saunders County, NE*), (b) from points in NE on and south of US Hwy 6, to points in SD on, east and north of a line beginning at the MN–SD State line, thence over US Hwy 16 to junction US Hwy 81, thence over US Hwy 81 to junction US Hwy 14, thence over US Hwy 14 to junction US Hwy 281, thence over US Hwy 281 to the ND–SD State line (points in Saunders County, NE*), (c) from points in NE on and south of US Hwy 30, to points in SD on and east of US Hwy 77 and on and north of US Hwy 18 (points in Saunders County, NE*). (Gateway eliminated: asterisked.)

No. MC–22254 (Sub-E2) (correction) filed May 14, 1974, published in the Federal Register August 29, 1979, corrected November 27, 1979, and republished this issue. Applicant: TRANS-AMERICAN VAN SERVICE, INC., P.O. Box 12608, Fort Worth, TX 76116. Representative: Elliott Bunce, suite 618, Perpetual Building, Washington, DC 20004. Two

typographical errors were reflected in the November 27, 1979, publication. Page 67798, third column, line 43, UT–NV should read UT–WY. Page 67799, column 3, line 45, Oswego should read Owego.

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-15997 Filed 5-23-80; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 80-3]

Gilbert Miller, M.D., Roslyn, N.Y.; Hearing

Notice is hereby given that on January 18, 1980, the Drug Enforcement Administration, Department of Justice issued to Gilbert Miller, M.D., Roslyn, New York, an Order To Show Cause as to why the Drug Enforcement Administration should not deny the application executed by Respondent on January 22, 1979 to possess, dispense, and distribute Schedule IIN, III, IIIN and IV controlled substances under Section 303 of the Controlled Substances Act (21 U.S.C. 823).

Thirty days having elapsed since the said Order To Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m. on Tuesday, June 3, 1980, in the Hearing Room, Room 1210, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C.

Dated: May 20, 1980.

William G. Fink,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 80-15969 Filed 5-23-80; 8:45 am]

BILLING CODE 4410-09-M

Personnel Instruction to Implement the Federal Employees Part-time Career Employment Act of 1978

AGENCY: Department of Justice.

ACTION: Proposed Departmental order.

SUMMARY: The Attorney General proposes to issue a Departmental Order to implement the Federal Employees Part-Time Career Employment Act of 1978 (the Act). This Order, which is required by the Act, would establish a continuing program to expand part-time career employment opportunities within all components of the Department of Justice except the Federal Bureau of Investigation.

DATE: Comments must be received on or before July 28, 1980.

ADDRESS: Comments to Warren Oser, Director, Personnel and Training Staff, Office of the Assistant Attorney General for Administration, Department of Justice, Room 1619, 10th and Pennsylvania Avenue, NW., Washington, D.C. 20530.

FOR FURTHER INFORMATION CONTACT: Mary S. Moore, Staffing Group, Personnel and Training Staff, Department of Justice, Room 1629, 10th and Pennsylvania Avenue NW, Washington, D.C. 20530. Phone: 202–633–3351.

SUPPLEMENTARY INFORMATION: Section 3(a) of the Federal Employees Part-time Career Employment Act of 1978 (the Act), 5 U.S.C. 3402, as amended, requires the head of each agency to "establish and maintain a program for part-time career employment" within his or her agency. Before such procedures are prescribed, they must be published in the Federal Register, and interested parties must be given the opportunity to comment. (See 5 U.S.C. 3406). These proposed procedures are being published for comment as required, and comments of all interested parties are invited. When final procedures are adopted, they will be promulgated as a Departmental Order in the Department of Justice Administrative Directive System. They will be internal personnel procedures and will not be codified in the Code of Regulations.

These proposed procedures comply with the requirements of 5 CFR Parts 340 and 890 and any final procedures must also comply with those requirements.

Dated: May 13, 1980.

Warren Oser,

Director, Personnel and Training Staff.

Accordingly, the Attorney General proposes, by the authority vested in him by 5 U.S.C. 301, 510, and 3402(a), to adopt the following Departmental Order to implement the Federal Employees Part-time Employment Act of 1978:

Table of Contents

Foreword

1. *Purpose.* This Order implements the Federal Employees Part-time Career Employment Act of 1978, 5 U.S.C. 3401 et. seq., by establishing a continuing program in the Department of Justice to provide career part-time employment opportunities.

2. *Scope.* The provisions of this Order apply to all organizational elements of the Department except the Federal Bureau of Investigation.

Kevin D. Rooney,

Assistant Attorney General for Administration.

Chapter 1—General Provisions

1. *Policy.* It is the policy of the Department of Justice to provide career part-time employment opportunities in positions through GS–15 or equivalent subject to agency resources and mission requirements. This policy recognizes the desirability of making maximum use of available human resources, including those qualified individuals who are available for part-time employment, and represents an opportunity to acquire talented workers who might otherwise not be available to the Department. Selections of part-time employees shall be made without regard to religion, race, color, national origin, marital status, sex, age, nondisqualifying physical handicap, political or labor organization affiliation, or personal favoritism.

2. *Authority.* The Federal Employees Part-Time Career Employment Act of 1978, as incorporated into Title 5, Code of Federal Regulations, Parts 340 and 890 as amended, narrows the definition of part-time career employment in the Federal Government from schedules of work less than 40 hours per week to regularly scheduled work of from 16 to 32 hours per week performed by individuals who are serving under competitive or excepted appointments in tenure groups I or II and who became employed on such a part-time basis on or after April 8, 1979. See Office of Personnel Management regulation 340.210 for a definition of these tenure groups.

The provisions of this Order should be used with the following: Pub. L. 95–437; 5 CFR Parts 340 and 890; FPM Bulletin 340–1; FPM Letter 890–22.

3. *Definitions.* As used in this Order, the following definitions will apply:

a. *Full-Time Employment.* Employment with work of 8 hours a day

and 40 hours a week within an administrative work week.

b. *Part-time Employment.* Regularly scheduled work of from 16 to 32 hours per week performed by individuals serving under competitive or excepted appointments in tenure groups I and II.

c. *Bureau.* For the purpose of this Order, the term "Bureau" refers to the Bureau of Prisons, the Immigration and Naturalization Service, the Drug Enforcement Administration, the United States Marshals Service, the law Enforcement Assistance Administration, the Executive Office for U.S. Attorneys, and collectively to the Offices, Boards, and Divisions, including the Community Relations Service, U.S. Parole Commission, and the Administrative Office for U.S. Trustees.

4. *Exceptions.* a. Employees with permanent appointments who were appointed on a part-time basis on or after April 8, 1979, are limited to work schedules not exceeding 32 hours per week. This prohibition does not apply to career part-time employees who were working on a permanent part-time basis on the effective date of the Act (April 8, 1979) so long as they continue to work on a part-time basis, do not have a break in service of more than three days, or leave their part-time schedule on other than a temporary basis.

b. In addition, the following positions are excluded from this Order by law:

(1) Positions located in the Federal Bureau of Investigation,

(2) Positions classified above GS–15 or equivalent,

(3) Positions where a collective bargaining agreement establishes the number of hours of employment per week,

(4) Positions which are temporary or intermittent, and

(5) Positions which are filled with career-seasonal employees who work under "mixed" tours of duty (i.e., varying periods of full-time, part-time, and intermittent service).

c. In order to carry out the mission of the Department, the following positions are also excluded from this Order:

(1) Law enforcement officers as defined in 5 USC 8331 (20), and

(2) Other positions in the Department which meet the criteria for administratively uncontrollable overtime, as set forth in DOJ Order 1551.4A.

d. The Attorney General, or designee, may authorize such additional exceptions as may be necessary for the Department to carry out its mission. However, in no cases will exceptions be authorized to permit regular tours of duty of 33 to 39 hours per week for part-time employees. (This in no way restricts the increase of a permanent part-time employee's actual hours of work above 32 hours per week for limited periods to meet heavy workloads, or provide for employee training, etc.)

e. Employment of part-time staff for less than 16 hours per week may be permitted when absolutely necessary to carry out the Department's mission.

Chapter 2.—Program Implementation

5. *Responsibilities.* a. *Assistant Attorney General for Administration.* The Assistant Attorney General for Administration provides overall program direction and leadership, establishes Department-wide policies and requirements, and designates a Part-time Career Employment Program Coordinator to give guidance and assistance to Department components in developing part-time career employment programs, and to maintain liaison with the Office of Personnel Management.

b. *Heads of Bureaus.* Heads of Bureaus are responsible for the proper administration of a part-time employment program within their respective organizations. In this regard, each shall ensure that:

(1) A systematic annual review is conducted at the end of each fiscal year with the purpose of establishing annual goals for part-time employment, and a timetable setting forth interim and final deadlines for achieving such goals.

(2) Implementing instructions are established governing the procedures and criteria to be used in connection with establishing or converting positions for part-time employment.

(3) A continuing review and evaluation of their part-time employment program is established under such instructions to monitor progress in expanding career part-time employment opportunities.

(4) Managers, supervisors, and employees under their jurisdiction are adequately informed of their rights and responsibilities under such instructions.

(5) Part-time employment activities are supportive of other special emphasis programs.

c. *Departmental Coordinator.* The Director, Personnel and Training Staff, Justice Management Division, is hereby designated as the Departmental Part-time Employment Coordinator. The Departmental Coordinator or his/her designee shall ensure that:

(1) Departmental regulations are issued and effectively implemented.

(2) Bureau level instructions implementing the basic provisions of this Order are in conformance with current laws, applicable Office of Personnel Management regulations, and the requirements of this Order.

(3) Goals and timetables developed by the bureaus within the Department are reviewed and monitored to assure progress in expanding part-time employment opportunities within the Department.

(4) Regular input from the Departmental Equal Employment Opportunity Staff is obtained in order to assure that specific needs for providing employment opportunities for minorities and women are addressed, and to assess the effect of the Departmental Part-time Employment Program on employment patterns and occupational concentration of minorities and women.

(5) Liaison is maintained with groups interested in promoting part-time employment opportunities, e.g., EEO, Federal Women's Program officials, the Handicapped Program Coordinator, representatives of employee organizations, etc.

(6) Consolidated Departmental reports on part-time employment are prepared for transmittal to the Office of Personnel Management.

(7) Bureau requests for advice and assistance on part-time employment have a proper response.

d. *Bureau Coordinators.* Personnel Officers within each bureau are hereby designated as Part-time Employment Coordinators with the responsibility for representing the heads of their respective organizations in the administration of the part-time employment program. The Bureau Coordinators' or their designees' responsibilities include the following:

(1) Overseeing development and implementation of part-time employment goals and timetables, coordinating with budget and ceiling control staffs, if necessary.

(2) Obtaining regular input from bureau officials of the Equal Employment Opportunity, Federal Women's and Hispanic Employment Programs to assure that goals and timetables address specific needs for providing employment opportunities for minorities and women, and to assess the effect of the bureau Part-time Employment Program on employment patterns and occupational concentration of minorities and women.

(3) Consulting on the bureau Part-time Employment Program with interested parties in special interest areas (e.g. employment of the handicapped, employment of veterans, and upward mobility) and with representatives of employee organizations, etc.

(4) Responding to requests for advice and assistance on part-time employment

for transmittal to the Departmental Coordinator.

(5) Maintaining bureau liaison with groups promoting part-time employment opportunities.

(6) Preparing reports on part-time employment for transmittal to the Departmental Coordinator.

(7) Monitoring progress in expanding part-time employment opportunities.

(8) Insuring that bureau managers, supervisors, and employees are kept informed on all aspects of the Part-time Employment Program which affect them.

6. Part-time Employment Goals and Timetables. a. Each bureau shall set annual nationwide goals for both establishing and converting positions for part-time career employment including a timetable with interim and final deadlines for achieving such goals. Goals for each fiscal year (beginning with fiscal year 1980) must be established and reported to the Departmental Coordinator by the end of the preceding fiscal year. Separate goals shall be established for newly established part-time career positions and conversion of full-time career positions to part-time career positions.

b. In establishing goals and timetables, bureaus are required to consider such criteria as:

(1) Agency mission and occupational mix;

(2) Workload fluctuations;

(3) Size of workforce, turnover rate, or employment trends;

(4) Affirmative action;

(5) Past experience with part-time employment (to include analysis of current part-time employment utilization);

(6) Patterns of overtime utilization;

(7) Potential for improving service to the public; and

(8) Personnel ceiling allowances and fiscal constraints.

7. *Reporting Requirements.* a. *Office of Personnel Management Reporting Requirements.* The Department is required to report twice each year to the Office of Personnel Management on progress in meeting part-time career employment goals, together with an explanation of impediments experienced in meeting such goals and measures taken to overcome them. These reports will be based on data as of March 31 and September 30 of each year, and they must be sent to the Office of Personnel Management by May 15 and November 15 respectively. The report to the Office of Personnel Management will be made by the Assistant Attorney General for Administration or his/her designee, and will be based on information provided by the bureaus.

b. *Department of Justice Reporting Requirements.* Bureau officials will send to the Director, Personnel and Training Staff, by May 1 and November 1 of each year, a statistical and narrative report showing for their respective organizations the following:

(1) Goals and timetables that were established.

(2) Progress toward meeting the goals.

(3) To the extent practicable, information concerning part-time career employment offers made during the period covered by the report to older individuals, handicapped individuals, or others who required a reduced workweek, persons with family responsibilities, or students.

(4) An explanation of any impediments in meeting goals or in otherwise carrying out the provisions of this instruction, together with a statement of the measures taken to overcome such impediments.

c. A Part-time Career Employment Report will be prepared by the Systems Operations Staff, Justice Management Division, on a quarterly basis for use in monitoring progress.

Chapter 3—Part-Time Employment Practices

8. *Vacancy Position Review.* Bureaus are required to establish procedures providing for all vacant positions covered by the Program to be reviewed for the feasibility of being filled on a part-time career employment basis. This review shall include consideration of criteria such as those used to establish goals and timetables.

9. *Establishment and Conversion of Part-Time Career Positions.* a. Bureaus are required to establish a sufficient number of new or converted part-time career positions to meet their established goals.

b. Bureaus which have not already done so shall develop procedures to permit employees to request and receive consideration to change from full-time to part-time schedules. Opportunities to voluntarily change from full-time to part-time employment shall be given to employees whenever feasible. However, no full-time employee shall be required to accept part-time employment as a condition of continued employment.

c. Bureaus shall not abolish any full-time position occupied by an employee for the sole purpose of making the duties of the position available to be performed on a part-time career employment basis.

10. *Notifying the Public of Part-Time Vacanices.* Bureaus shall develop procedures for notifying the public of vacant part-time positions. Generally, this will be done through vacancy announcements. As appropriate, vacancy listings, recruiting bulletins, or Federal job information announcements may also be used. In some cases, it will be desirable to publicize part-time opportunities by contacting schools and colleges, through professional journals or associations, or by contacting organizations having members who may want to work on a part-time basis.

11. *Program Review and Evaluation.* Review and evaluation of the Part-time Career Employment Program will be included in the periodic personnel management evaluation conducted by the Office of the Director, Personnel and Training. Evaluation will be based on evidence of such factors as:

a. Review of positions to identify functions suitable for part-time career work;

b. Issuance of internal policy statements and publications in support of part-time career employment.

c. Recruitment efforts made to employ part-time workers;

d. Increase in part-time career employment through conversions from full-time to part-time;

e. Increase in part-time career employment through new hires; and

f. Degree of achievement of affirmative action goals through part-time career employment.

Appendix 1.—Effects of Converting to Regularly Scheduled Part-Time Work

1. *Tenure.* There is no effect on protection against removal during or after the probationary or trial period. Probationary periods, trial periods and service requirements for career tenure (if the employee is in the competitive service) are computed on the basis of calendar time, the same as full-time employment. The Service Computation Date (SED) is undisturbed by part-time work. Since part-time employment constitutes a separate competitive level from full-time employment, part-time employees compete only with other part-time employees during a Reduction in Force (RIF).

2. *Earnings.* The rate of pay is dictated by the time schedule to work. Waiting periods for within-grade increases or eligibility for promotion are not affected; they are based on CALENDAR weeks of creditable service.

3. *Crediting Experience for Promotion Weights and Factors.* Part-time experience is credited on a pro-rata basis according to the relation it bears to a full workweek.

4. *Overtime.* Under the Fair Labor Standards Act, overtime begins after having completed 40 hours of work within a given workweek (excluding holidays and paid leave), regardless of

how many hours an employee works within a given workday.

5. *Leave.* Annual leave is earned on a pro-rata basis at the rate determined by years of service. Maximum carryover at the end of a leave year remains the same. Sick leave is earned at the rate of one hour for every 20 hours in pay status. No leave (annual or sick) is earned for hours worked in excess of 80 in a pay period. Part-time employees are NOT eligible for military leave.

Other leave categories (e.g., Absence Without Leave, Leave Without Pay. Court Leave, Funeral, Excused Absences) are not affected. For all categories of leave to which part-time employees are eligible, leave is charged only for absences during those hours the employee is scheduled to work.

6. *Holidays.* Holiday pay is received only if an employee is regularly scheduled to work on that day, and only for those hours an employee is regularly scheduled to work.

7. *Life Insurance Coverage.* The amount of insurance carried will automatically decrease whenever an employee's annual pay rate is decreased by an amount sufficient to lower pay to a difference $1,000 bracket (except that it cannot be lower than a $10,000 minimum insurance amount).

8. *Health Insurance Coverage.* Any employee whose employee status is changed, without a break in service, from full-time to part-time of 16 to 32 hours a week, and who is enrolled in a plan under the Federal Employees Health Benefits Program, may change his/her enrollment from one plan or option to another within 31 days from the effective date of the change in employment status. This change will affect the amount the government ordinarily contributes to the cost of health insurance coverage. These employees will receive a prorated contribution in an amount which is in direct proportion to the percentage of full-time service they regularly perform.

9. *Retirement Date Eligibility.* There is no effect on retirement date eligibility. Service is credited by calendar days.

10. *Retirement Annuity.* The computation is based on the highest average annual basic pay for any three consecutive years. Therefore, if years of part-time service are among the high three, annuity will be affected to the extent earnings were limited in those years.

[FR Doc. 80-16000 Filed 5-23-80; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Memoranda of Agreement Between the Occupational Safety and Health Administration and the Small Business Administration

AGENCY: Occupational Safety & Health administration and Small Business Administration.

ACTION: Memoranda of Agreement: (1) Regarding Resolution of Small Business Problems; (2) Regarding Flexibility in Rulemaking.

SUMMARY: The memorandum of agreement on resolution of small business problems in complying with OSHA regulations provides for cooperation between the two agencies towards solutions of these problems, with the SBA Chief Counsel for advocacy and the OSHA Special Assistant for Small Business responsible for coordinating these activities.

The memorandum of agreement on flexibility in rulemaking provides for interagency cooperation in promoting greater and more meaningful small business participation in the OSHA rulemaking process wherever possible in order to assure that any new rules and regulations issued by OSHA will be applied whenever possible in a flexible manner, taking into account the size and nature of the regulated businesses while fulfilling missions of the OSH Act of 1970 and the Small Business Act of 1958.

FOR FURTHER INFORMATION CONTACT: S. Kay Klatt, Special Assistant for Small Business, Occupational Safety & Health administration, U.S. Department of Labor, Rm. N3635, 200 Constitution Avenue NW., Washington D.C. 20210.

SUPPLEMENTARY INFORMATION: Smaller businesses have since OSHA's inception found it more difficult to comply with safety and health regulations than have their larger counterparts. It is OSHA's purpose to protect worker safety and health, not to create heavy burdens for the small business sector. Some of the burdens of compliance can be lessened or eliminated by flexibility in applying regulations and special attention to the unique problems of small businesses withouty compromising the mission of the OSH Act. The memoranda of agreement are set forth below.

Signed at Washington, D.C. this 16th day of May 1980.

Eula Bingham,

Assistant Secretary of Labor for Occupational Safety & Health.

Memorandum of Agreement Regarding Resolution of Small Business Problems Between the Occupational Safety and Health Administration and the Small Business Administration

Background

SBA makes available to small businesses financial, management, and technical assistance. The Office of the Chief Counsel for Advocacy is the focal point in the Small Business Administration (SBA) for aiding and counseling small businesses regarding policies and activities of Federal agencies as they affect small business.

The Occupational Safety and Health Administration (OSHA) is charged with the mission of providing a safe work place for employees and employers.

OSHA regulations affect many small employers. Small businesses' difficulties in complying with OSHA regulations are of interest to OSHA, the SBA and its Chief Counsel for Advocacy of small business.

Purpose

Purpose of this Memorandum of Agreement is the creation of procedures by which OSHA and the Small Business Administration (SBA) can cooperatively respond to problems experienced by small businesses in matters relating to both agencies.

Interagency Cooperation

The Special Assistant for Small Business on OSHA, and the Chief Counsel for Advocacy in SBA will be responsible for the coordination of activities under this Agreement at the national level.

Reponsibilites

SBA The SBA Administrator agrees to direct the SBA field and national office staffs to refer to the Chief Counsel for Advocacy all problems coming to their attention that involve small business relations with OSHA and SBA.

The Chief Counsel for Advocacy will provide staff resources to address these problems and to facilitate their speedy resolutions where possible.

OSHA The Assistant Secretary of the Department of Labor for Occupational Safety and Health agrees to direct the OSHA field and national office staffs to refer to the Special Assistant for Small Business all problems coming to their attention that involve both OSHA and SBA.

The Assistant Secretary agrees to provide resources within OSHA to address these problems and to facilitate their speedy resolution wherever possible.

Executed this 10th day of April 1980.

Eula Bingham,

Assistant Secretary of the Department of Labor for Occupational Safety and Health.

A. Vernon Weaver,

Administrator of the Small Business Administration.

Memorandum of Agreement Regarding Flexibility in Rulemaking Between the Occupational Safety and Health Administration and the Small Business Administration

1. *Purpose*

The purposes of this Memorandum of Agreement, agreed to by the Occupational Safety and Health Administration (OSHA) and the U.S. Small Business Administration (SBA) are:

(a) To assure that any new rules and regulations issued by OSHA will be applied whenever possible in a flexible manner, taking into account the size and nature of the regulated businesses while fulfilling missions of the Occupational Safety and Health Act of 1970 and the Small Business Act of 1958.

(b) To establish a program by means of which OSHA and SBA can work cooperatively to carry out the provisions of paragraph (a), thus providing the positive means of conveying to OSHA in connection with its standards-setting responsibilities, the special concerns and unique circumstances of small business.

2. *Interagency Coordination*

The Special Assistant for Small Business in OHSA and the Chief Counsel for Advocacy in SBA will be responsible for the coordination and implementation of activities under this Agreement.

3. *Implementation*

OSHA and the SBA, through its Chief Counsel for Advocacy, intend to promote flexibility in OSHA rule making by:

(a) Gathering and disseminating data and information during the rulemaking process as early as possible.

(b) Identifying small businesses by type of industry and industrial classification that may potentially be affected by the rule.

(c) Providing potentially affected small businesses opportunities, including public hearings and conferences, to present information, data, or their concerns to OSHA as early as possible during the rule-making process.

(d) Providing the Office of Advocacy and small businesses identified as potentially affected an opportunity to present suggested alternatives to minimize the financial and technical burdens of the proposed rule on small businesses.

(e) Providing information on special characteristics of affected small businesses in order to facilitiate the designing of educational, training, consultative programs to assist small businesses in meeting objectives of the rules.

4. *Cooperative Program*

(a) As early as possible in the rule-making process for which a regulatory analysis is being performed under the requirements of Executive Order 12044, or under the President's memorandum of November 16, 1979, OSHA will give notice to the Small Business Administration, through the Chief Counsel for Advocacy, of its intent to propose rules and guidelines and notice of data needed to implement flexible rule-making for small businesses.

(b) Upon such notice, the Chief Counsel for Advocacy will gather the requisite data from the small business community and transmit it to OSHA.

(c) The Chief Counsel for Advocacy will prepare analyses and recommendations on proposed rules. The Special Assistant for Small Business will consult with the Chief Counsel for Advocacy and small businesses on proposed rules and make appropriate recommendations to the Assistant Secretary.

(d) The Special Assistant for Small Business will also arrange for OSHA to furnish to any small business groups desiring to participate in OSHA rulemaking information of a technical nature that is necessary to a clear understanding of a rule, the rulemaking process or compliance with a rule.

Eula Bingham,

Assistant Secreary of the Department Labor for Occupational Safety and Health.

A. Vernon Weaver,

Administrator for the Small Business Administration.

Executed this 10th day of April 1980.

[FR Doc. 80-15945 Filed 5-23-80; 8:45 am]

BILLING CODE 4510-26-M

National Advisory Committee on Occupational Safety and Health; Full Committee Meeting and Subgroup Meeting

Notice is hereby given that the National Advisory Committee on Occupational Safety and Health (NACOSH) will meet in Washington, D.C. on June 12 and 13, 1980. On Thursday, June 12, the meeting will begin at 9:00 a.m. in Room N-5437 of the Frances Perkins Department of Labor Building (formerly the New Department of Labor Building), Third Street and Constitution Avenue N.W., Washington, D.C. On Friday, June 13, 1980 the Committee will meet at 9:00 a.m. in Room 800 of the Hubert H. Humphrey Building of the Department of Health and Human Services, Third Street and Independence Avenue, S.W., Washington, D.C. The public is invited to attend these meetings.

The National Advisory Committee was established under Section 7(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656) to advise the Secretary of Labor and the Secretary of Health, Education and Welfare of matters relating to the administration of the Act.

The meeting agenda will include reports on NIOSH research efforts and initiatives and OISHA legal development and other activities.

Written data or views concerning these agenda items may be submitted to the Division of Consumer Affairs. Such documents which are received before the scheduled meeting dates, preferably with 20 copies, will be presented to the Committee and included in the official record of the proceedings.

Anyone who wishes to make an oral presentation should notify the Division of Consumer Affairs before the meeting date. The request shoud include the amount of time desired, the capacity in which the person will appear and a brief outline of the content of the presentation. Oral presentations will be scheduled at the discretion of the chairman of the Committee to the extent which time permits.

For additional information contact: Clarence Page, Division of Consumer Affairs, Occupational Safety and Health Administration, Room N-3635, Third Street and Constitution Avenue, NW., Washington, D.C. 20210. Telephone 202-523-8024.

Official records of the meetings will be available for public inspection at the Division of Consumer Affairs.

Signed at Washington, D.C. this 20th day of May 1980.

Eula Bingham,

Assistant Secretary of Labor.

[FR Doc. 80-15946 Filed 5-23-80; 8:45 am]

BILLING CODE 4510-26-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Media Arts Panel (Media Art Centers); Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Media Arts Panel (Media Air Centers) to the National Council on the Arts will be held June 16, 1980 from 9:00 a.m.–5:30 p.m., and June 17, 1980 from 9:00 a.m.–5:30 p.m., in Room 1422 (June 16) and the 12th Floor Screening Room (June 17), Columbia Plaza Office Complex, 2401 E St., NW., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and 9(b) of section 552b of Title United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6070.

John H. Clark,
Director, Office of Council and Panel Operation, National Endowment for the Arts.
May 20, 1980.

[FR Doc. 80-15971 Filed 5-23-80; 8:45 am]
BILLING CODE 7537-01-M

OFFICE OF MANAGEMENT AND BUDGET

Agency Forms Under Review

May 21, 1980.

Background

When executive departments and agencies propose public use forms, reporting, or recordkeeping requirements, the Office of Management and Budget (OMB) reviews and acts on those requirements under the Federal Reports Act (44 USC, Chapter 35). Departments and agencies use a number of techniques including public hearings to consult with the public on significant reporting requirements before seeking OMB approval. OMB in carrying out its responsibility under the Act also considers comments on the forms and recordkeeping requirements that will affect the public.

List of Forms Under Review

Every Monday and Thursday OMB publishes a list of the agency forms received for review since the last list was published. The list has all the entries for one agency together and grouped into new forms, revisions, extensions, or reinstatements. Some forms listed as revisions may only have a change in the number of respondents or a reestimate of the time needed to fill them out rather than any change to the content of the form. The agency clearance officer can tell you the nature of any particular revision you are interested in. Each entry contains the following information:

The name and telephone number of the agency clearance officer (from whom a copy of the form and supporting documents is available);

The office of the agency issuing this form;

The title of the form;

The agency form number, if applicable;

How often the form must be filled out;

Who will be required or asked to report;

An estimate of the number of forms that will be filled out;

An estimate of the total number of hours needed to fill out the form; and

The name and telephone number of the person or office responsible for OMB review.

Reporting or recordkeeping requirements that appear to raise no significant issues are approved promptly. Our usual practice is not to take any action on proposed reporting requirements until at least ten working days after notice in the Federal Register but occasionally the public interest requires more rapid action.

Comments and Questions

Copies of the proposed forms and supporting documents may be obtained from the agency clearance officer whose name and telephone number appear under the agency name. The agency clearance officer will send you a copy of the proposed form, the request for clearance (SF83), supporting statement, instructions, transmittal letters, and other documents that are submitted to OMB for review. If you experience difficulty in obtaining the information you need in reasonable time, please advise the OMB reviewer to whom the report is assigned. Comments and questions about the items on this list should be directed to the OMB reviewer or office listed at the end of each entry.

If you anticipate commenting on a form but find that time to prepare will prevent you from submitting comments promptly, you should advise the reviewer of your intent as early as possible.

The timing and format of this notice have been changed to make the publication of the notice predictable and to give a clearer explanation of this process to the public. If you have comments and suggestions for further improvements to this notice, please send them to Jim J. Tozzi, Assistant Director for Regulatory and Information Policy, Office of Management and Budget, 726 Jackson Place, Northwest, Washington, D.C. 20503.

DEPARTMENT OF AGRICULTURE

Agency Clearance Officer—Richard J. Schrimper—447–6201

New Forms

Economics, Statistics, and Cooperatives Service
Performance of cooperatives and selected proprietary firms
Other (see SF–83)
Selected cooperatives and proprietary firms, 440 responses; 550 hours
Office of Federal Statistical Policy and Standard, 673–7974

DEPARTMENT OF COMMERCE

Agency Clearance Officer—Edward Michals—377–3627

New Forms

Bureau of the Census
1980 IRS taxpayer resident questions
Single time
Tax filers, 94,896,000 responses; 1,581,600 hours
William T. Adams, 395–4814

Bureau of the Census
1980 census education project evaluation survey
S530, S531
Single time
Principals and teachers, 2,000 responses; 166 hours
William T. Adams, 395–4814

Industry and Trade Administration
Rubber tire building machinery
ITA–9030
Single time
Manufacturers of rubber tire building machinery, 45 responses; 45 hours
William T. Adams, 395–4814

Revisions

National Oceanic and Atmospheric Administration
Stone crab (amendment to commercial fisheries logbook family of forms)
NOAA 88–176 & 153
Monthly

Captains of fishing craft, 223,370 responses; 8,577 hours
William T. Adams, 395–4814

DEPARTMENT OF ENERGY

Agency Clearance Officer—John Gross—633–9770

New Forms

RECS-housing unit record sheet and household questionnaire
EIA–457A, B
Annually
Households in United States, 11,000 responses; 11,183 hours
Jefferson B. Hill, 395–7340

RECS–quarterly survey of Fuel Oil Households
EIA–457D
Quarterly
Households in the United States, 7,200 responses; 1,800 hours
Jefferson B. Hill, 395–7340

RECS–Rental agent questionnaire
EIA–457C
Other (see SF–83)
Rental agents, 920 responses; 230 hours
Jefferson B. Hill, 395–7340

RECS–electric and gas utility, and fuel oil and LPG
Supplier forms
EIA–457E–H
Annually
Electric and gas utility fuel oil and LPG dealers, 1,200 responses; 10,270 hours
Jefferson B. HIll, 395–7340

Request for priority rating for energy programs
PR–437
On occasion
Anyone needing materials to complete energy projects, 100 responses; 200 hours
Jefferson B. Hill, 395–7340

Revisions

Report of underground natural gas storage
EIA–191
Other (see SF–83)
Intrastate natural gas storage companies, 672 responses; 2,688 hours
Jefferson B. Hill, 395–7340

Survey of fuel oil and motor gasoline dealers-retail, wholesale, and bulk stations
B–1156–1161 1161
Monthly
Fuel oil and motor gasoline dealers, 32,604 responses; 13,140 hours
Jefferson B. Hill, 395–7340

Request for assignment of a supplier and/or base period
ERA–99
On occasion
Wholesale purchasers bulk end-users of petroluem products, 40,000 responses; 320,000 hours
Jefferson B. Hill, 395–7340

Reinstatements

Epidemiology survey on magnetic effects on human health (questionnaire)
XBG–504–510
Single time
Individuals exposed to magnetic fields and control group, 2,200 responses; 540 hours
Jefferson B. Hill, 395–7340

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Agency clearance officer—Joseph J. Strnad—245–7488

New Forms

National Institutes of Health
Health message testing service
Single time
Adult, male/female population, 8,840 responses; 2,210 hours
Richard Eisinger, 395–6880

National Institutes of Health
Audiovisual evaluation form
Other (see SF–83)
U.S. health professionals who borrow audiovisuals from NMAC, 18,000 responses; 900 hours
Richard Eisinger, 395–6880

DEPARTMENT OF THE INTERIOR

Agency Clearance Officer—William L. Carpenter—343–6716

Reinstatements

Bureau of Land Management
Desert land entry assignment claim
2520–2
On occasion
Desert land entry applicants, 500 responses; 250 hours
Charles A. Ellett, 395–7340

DEPARTMENT OF LABOR

Agency Clearance Officer—Paul E. Larson—523–6341

New Forms

Employment and Training Administration
Extended benefit trigger rates without EB claims
ETA–RC32
Single time
State employment security agencies, 53 responses; 106 hours
Arnold Strasser, 395–6880

Revisions

Bureau of Labor Statistics
CPI rents
BLS 2921 B, C, D
Semi-annually
Households, 4,200 responses; 7,000 hours
Office of Federal Statistical Policy and Standard, 673–7974

GENERAL SERVICES ADMINISTRATION

Agency Clearance Officer—John F. Gilmore—566–1164

New Forms

Building service contractor work report
GSA 3430
Weekly
Description not furnished by agency, 28,080 responses; 14,040 hours
Kenneth B. Allen, 395–3785

NATIONAL SCIENCE FOUNDATION

Agency Clearance Officer—Herman Fleming—357–7811

New Forms

Survey of chief officers—instruments industry
Single time
SCI instruments manufacturers, 1,443 responses; 1,082 hours
Office of Federal Statistical Policy and Standard, 673–7974

International scientific activity questionnaire
Single time
Participants in INT programs, 11,430 responses; 8,572 hours
Marsha D. Traynham, 395–7340

TENNESSEE VALLEY AUTHORITY

Agency Clearance Officer—Eugene E. Mynatt—854–2596

Extensions

Prevailing wage for TVA construction work—data from local unions
3523
Annually
350 local unions, 50 contractors or contractor associations, 400 responses; 200 hours
Charles A. Ellett, 395–7340

VETERANS ADMINISTRATION

Agency Clearance Officer—R. C. Whitt—389–2146

Revisions

Notice of default
26–6850
On occasion
Lenders or holders, 90,000 responses; 15,000 hours
Laverne V. Collins, 395–6880

Extensions

Request for information from witness to accident of claimant veteran
FL21–806
On occasion
Witnesses, 13,200 responses; 4,400 hours
Laverne V. Collins, 395–6880

Reinstatements

Claim for payment of suspense of other credits due estate of deceased

veteran—National Service Life Insurance
29-4338
on occasion
Administrators or executors of estates, 1,000 responses; 167 hours
Laverne V. Collins, 395-6880

C. Louis Kincannon,

Acting Deputy Assistant Director for Reports Management.

[FR Doc. 80-16001 Filed 5-23-80; 8:45 am]

BILLING CODE 3110-01-M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Trade Policy Staff Committee; Hearings on Possible Suspension of Concessions on Lead With Regard to Mexico

On October 31, 1979, pursuant to section 101(a)(1) of the Trade Act of 1974 (the Trade Act) (19 U.S.C. 2111(a)(1)), the United States entered into a trade agreement with the United Mexican States. The agreement, which contemplated Mexican accession to the General Agreement on Tariffs and trade (GATT), granted concessions on the following:

Litharge: Provided for in item 473.52 of the Tariff Schedules of the United States (TSUS) (19 U.S.C. 1202)
Red Lead: Provided for in TSUS item 473.56; and
Unwrought Lead: Provided for in TSUS items 624.02 and 624.03.

The United States implemented the concessions in Presidential Proclamation 4707 of December 11, 1979. On March 18, 1980, the President of the United Mexican States announced that Mexico would not accede to the GATT, contrary to the expectations on which the October 31, 1979 trade agreement was based. Negotiations between the United States and Mexico may be conducted on the question of compensation.

Section 125(d) of the Trade Act (19 U.S.C. 2135(d)) would authorize the withdrawal, suspension or modification of the application of trade agreement obligations, such as those granted on the above listed items, which benefit a foreign country which withdraws, suspends, or modifies the application of a trade agreement obligation of benefit to the United States without granting adequate compensation. The section allows an increase in duties, as appropriate, to effect adequate compensation.

The Trade Policy Staff Committee (TPSC) is considering recommending to the President that the concessions on the above listed products be suspended with respect to Mexico, on or about June 20, 1980. In accordance with the requirements of section 125(f) of the Trade Act (19 U.S.C. 2135(f)), the TPSC will conduct a public hearing giving interested persons an opportunity to produce evidence and to comment on the proposed suspension of concessions. The hearing will be held at 10:00 a.m. on June 12, 1980, at the Office of the United States Trade Representative, 1800 G Street, NW., Room 730, Washington, D.C.

Parties wishing to present evidence or to make comments at the hearing should submit their request for inclusion on the agenda along with 20 copies of their statement to Carolyn Frank, Secretary of the Trade Policy Staff Committee, Room 735, 1800 G Street, NW., Washington, D.C. 20506, no later than June 6, 1980. Parties wishing to submit written comments should send 20 copies of their comments to the Secretary at the above address no later than June 13, 1980.

For further information, call Jon Rosenbaum (202) 395-6971.

Ann H. Hughes,

Chairman, Trade Policy Staff Committee.

[FR Doc. 80-15981 Filed 5-23-80; 8:45 am]

BILLING CODE 3190-01-M

RAILROAD RETIREMENT BOARD

Determination of Quarterly Rate of Excise Tax for Railroad Retirement Supplemental Annuity Program

In accordance with directions in section 3221(c) of the Railroad Retirement Tax Act (26 U.S.C. 3221(c)), the Railroad Retirement Board has determined that the excise tax imposed by such Section 3221(c) on every employer, with respect to having individuals in his employ, for each work-hour for which compensation is paid by such employer for services rendered to him during the quarter beginning July 1, 1980, shall be at the rate of twelve and one-half cents.

In accordance with directions in Section 15(a) of the Railroad Retirement Act of 1974, the Railroad Retirement Board has determined that for the quarter beginning July 1, 1980, 20.3 percent of the taxes collected under Sections 3211(b) and 3221(c) of the Railroad Retirement Tax Act shall be credited to the Railroad Retirement Account and 79.7 percent of the taxes collected under such Sections 3211(b) and 3221(c) plus one hundred percent of the taxes collected under Section 3221(d) of the Railroad Retirement Tax Act shall be credited to the Railroad Retirement Supplemental Acccount.

Dated: May 15, 1980.

By Authority of the Board.

R. F. Butler,

Secretary of the Board.

[FR Doc. 80-15940 Filed 5-23-80; 8:45 am]

BILLING CODE 7905-01-M

SMALL BUSINESS ADMINISTRATION

Memoranda of Agreement Between the Occupational Safety and Health Administration and the Small Business Administration

Cross Reference: For a document stating the Memoranda of Agreement regarding the resolution of small business problems and the flexibility in rulemaking, see FR Doc. 80-15945 appearing in the Notices Section of this issue under the Occupational Safety and Health Administration, Department of Labor.

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD 80-061]

Delegation of Authority To Determine Unsafe Voyages

ACTION: Notice of Redelegation.

EFFECTIVE DATE: May 20, 1980.

This notice announces that the Commander, 7th Coast Guard District has been authorized to redelegate authority contained in 33 CFR 1.05-1(d) to Commanding Officers of Coast Guard units under his operational command, in connection with voyages relating to the Cuban refugee exodus.

The redelegation has become imperative due to the unsafe conditions observed recently as a large flotilla of vessels of various types, in widely differing degrees of seaworthiness, have been engaged in transporting refugees from Cuba to the United States.

This allows those Commanding Officers to whom the Commander 7th Coast Guard District has redelegated this authority to take necessary action on the scene to prevent manifestly unsafe voyages.

Dated: May 21, 1980.

J. B. Hayes,

Admiral, U.S. Coast Guard Commandant.

[FR Doc. 80-16043 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-14-M

[CGD 80-034]

Notification of LORAN-C Overprint Chart Requirement

SUMMARY: This notice is published to ensure that operators of vessels of 10,000 gross tons or more that apt to use LORAN-C receivers in accordance with 33 CFR 164.41 are aware of the related requirement under 33 CFR 164.33 to carry the most current charts with LORAN-C overprints.

FOR FURTHER INFORMATION CONTACT: Mr. Laurence E. Stephey, Office of Marine Environment and Systems (G-WWM-2), Room 1608, Department of Transportation, U.S. Coast Guard Headquarters, 2100 Second St., SW., Washington, D.C. 20593, (202) 426-4958.

DISCUSSION: On June 1, 1980, pursuant to 33 CFR 164.41 all vessels of 10,000 gross tons or more calling at ports in the continental U.S., including Alaska south of Cape Prince of Wales, must carry an electronic position fixing device. Tank vessels of 10,000 gross tons or more have been required to carry these devices since June 1, 1979. LORAN-C receivers are among the devices that may be used to comply with the requirement.

Some LORAN-C receivers however, have a coordinate conversion capability that displays the vessel's position in terms of latitude and longitude. These receivers convert incoming LORAN-C signals into geographic coordinates based on theoretical over water radio propagation. The retardation of LORAN-C signals caused by the overland path of radio waves is not reflected by these receivers. Failure to account for these retarded signals will produce errors in position fixing. These same errors will occur by using the Defense Mapping Agency's LORAN-C tables as they similarly do not compensate for over-land signal retardation.

LORAN-C lines on the most current charts (with LORAN-C overprints) are adjusted to provide for over-land radio wave retardation with the necessary degree of accuracy for those vessels operating within the U.S. coastal confluence zone. For this reason, 33 CFR 164.41 requires vessels to have LORAN-C receivers that read out in Time Differences and 33 CFR 164.33 requires vessels to carry charts that are the most recently published and available for the area and currently corrected. Therefore, those vessels that utilize a LORAN-C receiver to comply with § 164.41 must also carry the most current charts with LORAN-C overprints.

Dated: May 15, 1980.

K. G. Wiman,

Captain, U.S. Coast Guard, Acting Chief, Office of Marine Environment and Systems.

[FR Doc. 80-16026 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-14-M

National Highway Traffic Safety Administration

National Highway Safety Advisory Committee; Public Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. I), notice is hereby given of a meeting of the National Highway Safety Advisory Committee to be held on June 17, 18, and 19, 1980.

The meetings will start at 9:00 a.m., on all three days. The full committee will be in session on the first day to review and vote on several major reports. They are: 55 mph national speed limit; future vehicle mix problems and countermeasures; driver, highway, vehicle compatibility issues; and emergency medical services, feasibility of "third service" concept.

The second day will be devoted to individual Task Force meetings (to finish up this session's business). On June 19, the full Committee will present the reports that have been approved to Secretary Goldschmidt.

All meetings will be held in the DOT Headquarters Building, 400 Seventh Street, SW., Washington, D.C. in room 2230. Attendance is open to the interested public, but limited to the space available. Members of the public may present a written statement to the Committee at any time.

This meeting is subject to the approval of the appropriate DOT officials. Additional information may be obtained from the NHTSA Executive Secretary, Room 5221, 400 Seventh Street, SW., Washington, D.C. 20590, telephone 202-426-2872.

Issued in Washington, D.C. on May 19, 1980.

Wm. H. Marsh,

Executive Secretary.

[FR Doc. 80-15824 Filed 5-23-80; 8:45 am]

BILLING CODE 4910-59-M

Office of the Secretary

Information Security Policy; Directives Concerning the Classification, Declassification and Control of National Security Information

AGENCY: Department of Transportation.

ACTION: Notice of directives concerning information security policy.

SUMMARY: The Department of Transportation is required by Section 5-402 of Executive Order 12065 of June 28, 1978, to publish in the Federal Register unclassified regulations that establish agency security policy and unclassified guidelines for systematic declassification review. Department of Transportation (DOT) Orders 1640.3C and 1640.4B constitute these regulations and guidelines. This notice publishes the directives, except for those portions that do not significantly affect the public. The directives are unclassified and are available for inspection in their entirety at the address below.

FOR FURTHER INFORMATION CONTACT: David A. Grand, Acting Director of Security, Department of Transportation, 400 7th Street, SW., Washington, D.C. 20590, Room 10401. The telephone number for this office is (202) 426-4677. The office is open from Monday thru Friday, 9:00 a.m. to 5:30 p.m., e.t.

Issued in Washington, D.C., on May 9, 1980.

Neil Goldschmidt,

Secretary of Transportation.

[DOT 1640.3C]

National Security Information

November 21, 1979.

1. *Purpose.* This Order provides for implementing Executive Order 12065, National Security Information.

2. *Cancellation.* DOT 1640.3B, National Security Information, of 8-22-79.

3. *Background.*

a. On June 28, 1978, the President issued Executive Order (E.O.) 12065 and revoked E.O. 11652, as amended, Classification and Declassification of National Security Information and Material.

b. The objective of the new Order is to increase openness in government by limiting classification and accelerating declassification. At the same time, it provides for the protection of legitimate national security secrets.

c. The National Security Council provides overall policy direction for the national security information program. An Information Security Oversight Office was established with responsibility to oversee agency actions to ensure compliance with the Order and to promulgate with the approval of the National Security Council, directives for the implementation of the Order.

4. *Authority for Original Classification of Information*

a. E.O. 12065 confers upon the Secretary of Transportation the authority to originally classify

information as Secret and Confidential with further authorization to delegate this authority. (No official of the Department of Transportation (DOT) has authority to originally classify information as Top Secret.)

b. The following delegations of authority, which may not be redelegated, are hereby made:

(1) *Office of the Secretary (OST).* The Director of Investigations and Security.

(2) *U.S. Coast Guard (USCG).* The Commandant; Chief, Office of Operations.

(3) *Federal Aviation Administration (FAA).* The Administrator, Director of Investigations and Security.

c. At such time as Defense Readiness Condition Number Two or higher emergency condition may be declared, authority to originally classify information as Secret and Confidential is automatically delegated to the officials named below. This authority, which may not be redelegated, is automatically cancelled when Defense Readiness Condition Number Three or lower emergency level is declared.

(1) *OST.* Deputy Secretary; Assistant Secretary for Policy and International Affairs; Assistant Secretary for Administration.

(2) USCG. Vice Commandant; Chief of Staff; Commander, Atlantic Area; Commander, Pacific Area; Commanders, Coast Guard Districts; Commander, Coast Guard Activities Europe; Chief, Intelligence and Security Division.

(3) *FAA.* Deputy Administrator; Directors, FAA Regions and Centers.

d. Although the delegations of authority are expressed above in terms of positions, the authority is personal and is vested only in the individual occupying the position. The authority may not be exercised "by direction of" a designated official. The formal appointment or assignment of an individual to one of the identified positions or a designation in writing to act in the absence of one of these officials, however, conveys the authority to originally classify information.

5. DOT Security Review Committee.

a. In accordance with the provisions of E.O. 12065, a DOT Security Review Committee is established and shall have authority to:

(1) act on all suggestions and complaints not otherwise resolved with respect to the Department's administration of E.O. 12065 and implementing directives, including those regarding overclassification, failure to declassify, or delay in declassifying, and

(2) act on appeals of requests for classification reviews, and appeals of requests for records under Section 552 of Title 5, U.S.C. (Freedom of Information Act) and E.O. 12065 when the initial denial was based on continued classification of the record.

b. The DOT Security Review Committee shall be composed of the Assistant Secretary for Administration who shall serve as Chairman, the General Counsel, and the Director of Investigations and Security. When matters affecting a particular operating element are at issue, the Associate Administrator for Administration of that operating element or the Chief of Staff for the U.S. Coast Guard shall participate as an ad hoc member, together with the Chief Counsel for the particular element.

6. *Action.* The Assistant Secretary for Administration shall ensure effective compliance with and implementation of E.O. 12065. In this regard, he shall conduct an active oversight program. Within the framework of E.O. 12065, he shall issue DOT-wide policy and procedural instructions.

Neil Goldschmidt,
Secretary of Transportation.

[Order 1640.4B]

Classification, Declassification, and Control of National Security Information

February 11, 1980.

1. *Purpose.* This Order implements Executive Order 12065, National Security Information, Executive Order 10865, Safeguarding Classified Information Within Industry, and Department of Transportation Order 1640.3C, National Security Information.

2. *Cancellation.* a. DOT order 1640.4A, CLASSIFICATION, DECLASSIFICATION, AND CONTROL OF NATIONAL SECURITY INFORMATION, of 8-24-79 and 1-16-80.

3. *Reference.* DOT 1640.3C, National Security Information, authorizes the Assistant Secretary for Administration to issue DOT policy and procedural instructions to implement E.O. 12065 and to ensure effective compliance with the provisions of the Executive Order. DOT 1640.3C designated those Departmental officials who have authority to originally classify information.

4. *Assignments.*

a. In addition to other actions directed by this Order, the Director of Investigations and Security, Office of the Secretary, shall evaluate the overall application of and adherence to security policies and requirements prescribed herein and report his findings and recommendations to the Assistant Secretary for Administration and, as appropriate, to the heads of operating administrations and the Secretary. The Director shall be the Departmental point of contact with the Information Security Oversight Office, established by E.O. 12065, and shall furnish such information as that office may require. The Director shall develop changes to Departmental directives which may be needed to comply with amendments to E.O. 12065, supplementing instructions from the National Security Council, or resulting from changed conditions.

b. Secretarial Officers and Heads of Operating Administrations shall assure: (1) The effective administration of the provisions prescribed; (2) That adequate personnel and funding are provided for this purpose, and; (3) That corrective actions which may be warranted are taken promptly.

5. *Approval.* The provisions of this Order have been approved by the Information Security Oversight Office (ISOO) pursuant to the provisions of E.O. 12065.

For the Secretary of Transportation.
Edward W. Scott, Jr.,
Assistant Secretary for Administration.

Paragraph

Chapter I.—General

1-1. Discussion

a. The interests of the United States and its citizens are best served by making information regarding the affairs of Government readily available to the public. This concept of an informed citizenry is reflected in the Freedom of Information Act and in the current public information policies of the Executive Branch.

Within the Federal Government there is some official information and material which, because it bears directly on the effectiveness of our national defense and the conduct of our foreign relations, must be subject to some constraints for the security of our Nation and the safety of our people and our allies. To protect against actions hostile to the United States, of both an overt and covert nature, it is essential that such official information and material be given only limited dissemination.

To ensure that such information and material is protected, but only to the extent and for such period as is necessary, this order identifies the information to be protected, prescribes classification, downgrading, declassification and safeguarding procedures to be followed, and establishes a monitoring system to ensure its effectiveness.

b. This Departmental order is intended to achieve a coordinated and uniform policy throughout DOT in

maintaining the security of classified information. It is applicable to all classified information in the custody of DOT regardless of whether the information or material was produced within DOT or originated outside DOT and released to it.

1–2. Security Principles

a. Official information which requires protection against unauthorized disclosure in the interest of the national defense or foreign relations of the United States (hereinafter collectively termed "national security") is designated classified information. Classification of information shall be solely on the basis of national security considerations. Information no longer having significance to national security shall be declassified.

b. Knowledge or possession of classified information shall be permitted only to persons whose official duties or contractual obligations require such access, and only if they have been determined to be trustworthy. Unless both standards are met, i.e., need-to-know and trustworthiness, the individual obtaining access is an unauthorized person and his gaining access constitutes an unauthorized disclosure.

c. The policies, standards, and requirements estalished by this order are designed to assure proper classification/declassification of information and to prevent unauthorized persons from gaining knowledge of information designated as classified. These principles shall be kept foremost in mind when local procedures are developed to implement the provisions of this order.

1–3. *Security Planning.* Security is not an end to itself. Rather, it is an integral part of operations and of program administration. Accordingly, managers of programs or projects which may involve classified information shall consult with the appropriate security element to assure that security planning, to include classification and declassification planning, is provided at the outset and as the project develops.

1–4. *Order Format and Use.* This order is designed to be both a statement of Departmental policies and requirements and an employee operating manual. Headquarters, facility and office implementing procedures should be filed in the appropriate Chapter. In this way the reader may find easily and quickly the answers and guidance he is seeking. Requests for any modification or deviation from this Order, including supporting justification shall be submitted to the OST Director of Investigations and Security, M–50, through appropriate channels.

1–5. *Notification by Field Activities of Classified Material Held.* Field activities shall advise the security element of the appropriate region, district or national headquarters when any of the following occur:

a. An activity which does not have custody of classified material receives such material. The notification shall include a statement as to the highest classification category of the material received.

b. The highest classification category of material held changes. For example, an activity which holds CONFIDENTIAL material receives SECRET material, or an activity having had both SECRET and CONFIDENTIAL material destroys or otherwise gives up custody of the SECRET material.

c. An activity which had custody of classified material no longer possesses such material.

Chapter II—Security Classification

2–1. General

a. Information may be classified initially and be retained in a classified status only if:

(1) It meets one or more of the classification criteria specified in paragraph 2–4 below, and

(2) Its unauthorized disclosure reasonably could be expected to cause identifiable damage to the national security.

b. It is emphasized that *only information is classified.* Classifed information requires protection regardless of the medium by which it is revealed or expressed. It may be expressed orally, in writing or printed form, or embodied in equipment. Terms such as "classified document", "classified material", "classified letter", etc. are simply easy reference terms to describe items that contain or reveal classified information.

c. Once information is classified, the entire spectrum of security controls are brought into play to protect it. Information which does not require protection (unwarranted initial or continuing classification) or which does not require the degree of protection to which it is assigned (overclassification) can derogate the protection afforded information which is truly significant, generate unnecessary security costs, and impede the flow of information to the public to which it is entitled. Accordingly, judicuous and timely classification, downgrading and declassification actions are required.

2–2. *Classification Designations.* Official information which requires protection against unauthorized disclosure in the interest of national security shall be classified in one of three designations, namely TOP SECRET, SECRET, or CONFIDENTIAL, depending upon the degree of significance to the national security. If there is reasonable doubt as to which classification designation is appropriate or whether the information should be classified at all, the least restrictive designation should be used—or the information should be classified. The classification designations are defined as follows:

a. *Top Secret.* Shall be applied only to information which, through unauthorized disclosure, could reasonably be expected to cause exceptionally grave damage to the national security.

b. *Secret.* Shall be applied only to information which, through unauthorized disclosure, could reasonably be expected to cause serious damage to the national security.

c. *Confidential.* Shall be applied to information which, through unauthorized dislosure, could reasonably be expected to cause identifiable damage to the national security.

2–3 Prohibition of Use of Other Terms

a. No other designations shall be used to identify classified information, except as expressly provided by statute.

b. No other terms, such as "Sensitive", "Conference", "Agency", "Administratively", etc., shall be used in DOT in conjunction with formal classification designation terms defined in paragraph 2–2 above.

c. The terms "For Official Use Only" and "Limited Official Use" do not designate classified information. They are used to identify unclassified information which requires protection against uncontrolled release. (See DOT Order 1640.1.)

2–4. *Classification Criteria.* Information may not be considered for classification unless it concerns:

a. Military plans, weapons, or operations;

b. Foreign government information;

c. Intelligence activities, sources, or methods;

d. Foreign relations or foreign activities of the United States;

e. Scientific, technological, or economic matters relating to the national security;

f. U.S. Government programs for safeguarding nuclear materials or facilities; or

g. Other categories of information which are related to national security and which require protection against

unauthorized disclosure as determined by the President, officials with TOP SECRET classification authority, or by the Secretary of Transportation with respect to DOT developed information. Recommendations concerning need for any such additional category of information which may be considered for original classification shall be forwarded through the appropriate headquarters security element to the OST Office of Investigations and Security for a decision by the Secretary. If the Secretary determines that such additional category is warranted, the OST Director of Investigations and Security shall so advise the Director of the Information Security Oversight Office (ISOO).

Note.—Unauthorized disclosure of foreign government classified information or the identity of a confidential foreign source is presumed to cause at least identifiable damage to the national security.

2–5. Prohibitions on Classifying Information

a. Classification may not be used to conceal violations of law, inefficiency or administrative error; to prevent embarrassment to a person, organization or agency; or to restrain competition.

b. Basic scientific research information not clearly related to the national security may not be classified.

c. A product of non-Government research and development that does not incorporate or reveal classified information to which the producer or developer was given prior access may not be classified until and unless the Government acquires a proprietary interest in the product. This prohibition does not affect the provisions of the Patent Secrecy Act of 1952 (35 U.S.C. 181–188).

d. References to classified documents that do not disclose classified information may not be classified or used as a basis for classification.

e. Classification may not be used to limit dissemination of information that is not classifiable under the provisions of this Order or to prevent or delay the public release of such information.

f. No document originated on or after December 1, 1978, may be classified after receipt of a request for the document under the Freedom of Information Act or the Mandatory Review provisions (paragraph 3–10) unless such classification is consistent with this Order and is authorized by the Secretary. Documents originated before December 1, 1978, and subject to such a request may not be classified unless such classification is consistent with this Order and is authorized by the Secretary or the Director of Investigations and Security.

g. Classification may not be restored to documents already declassified and released to the public.

2–6. Classification Process

a. Classification should be the result of a balanced judgment. There must be a positive basis for classification. If there is reasonable doubt, after due consideration, whether the information warrants classification or not, the information should *not* be classified.

b. An evaluation of information forms the basis for classification. A document or other material is classified either because of the information it contains, which may be ascertained by study, analysis, observation or use of it, or because of the information it may reveal when associated with other information, including that which the classifier knows has been officially released to the public.

c. Classification determinations must be preceded by an exact identification of each item of information which may require security protection. This process involves identification of that specific information which comprises the basis for the particular national advantage which would or could be damaged, minimized or lost if the information were compromised, thereby adversely affecting the national security.

d. A determination to classify shall be made initially by an original classification authority and only when (1) the information meets one or more of the criteria set forth in paragraph 2–4 above, and (2) the unauthorized disclosure of the information reasonably could be expected to cause at least identifiable damage to the national security. The determination involved in the first step is separate and distinct from that of the second step. The fact that the information falls under one or more of the classification criteria shall not be presumed to mean that the information *automatically* meets the damage criteria.

2–7. Distinction Between Original and Derivative Classifications

a. There are two types of classification actions—original and derivative. Both require that judgments be made, and the provisions of the Classification Designation, Classification Criteria, Prohibitions on classifying and Classification Process set forth above apply equally to both.

b. Original classification, however, is the more important of the two. It results in the initial production of classified material and is the basis for all derivative classification actions. Because of this, only specifically designated officials are authorized to make original classification determinations.

c. Original classification is an initial determination that information requires protection against unauthorized disclosure in the interest of national security and a designation of the level of classification. The reasons why unauthorized disclosure of the information could adversely affect the national security is the critical judgment factor in an original classification determination.

d. Once an original classification decision is made, many new documents which relate directly to the subject matter or substance of the original decision may be produced by many different offices. The classification of the new documents is derived from the initial classification determination, and classifying these documents does not constitute an original classification action.

e. The classification of most classified documents produced within DOT is derived from an original classification determination made by an official outside DOT. Although the DOT documents will contain information which is new and is developed by DOT, this information would not require protection in the interests of national security based solely on carrying out DOT functions. Rather, the reasons why the information requires protection are established by an original classification authority in the Department of Defense (DOD), State Department, etc. For example, certain DOT-produced documents pertaining to marine or maritime operations or to the control of air traffic are classified because they relate to support provided to DOD programs and reveal information which an appropriate DOD official has determined requires protection. Therefore, a derivative classification is assigned to the DOT produced material.

f. In some instances, DOT develops information which is not related to or does not pertain to a classification determination made at another agency. In these instances, the reasons why the information requires protection in the interests of national security are unique to DOT. Therefore, an original classification determination needs to be made. The provisions of paragraphs 2–8, 2–9, and 2–11 below apply to information originally classified by DOT. The provisions of paragraphs 2–12 and 2–13 below apply to information derivatively classified by DOT.

2-8. Authority to Make Original Classification Determinations

a. E.O. 12065 confers upon the Secretary of Transportation the authority to originally classify information as SECRET and CONFIDENTIAL with further authorization to delegate this authority.

b. The Secretary has delegated authority, which may not be redelegated, to:

(1) OST—the Director of Investigations and Security.

(2) USCG—the Commandant; Chief of Operations.

(3) FAA—The Administrator, Director of Investigations and Security.

c. At such time as Defense Readiness Condition Number Two or higher emergency condition may be declared, authority to originally classify information as SECRET or CONFIDENTIAL is automatically delegated to the officials named below. This authority, which may not be redelegated, is automatically cancelled when Defense Readiness Condition Number Three or lower emergency level is declared.

(1) OST—Deputy Secretary; Assistant Secretary for Policy and International Affairs; Assistant Secretary for Administration.

(2) USCG—Vice Commandant; Chief of Staff; Commander, Atlantic Area; Commander, Pacific Area; Commanders, Coast Guard Districts; Commander, Coast Guard Activities Europe; Chief, Intelligence and Security Division.

(3) FAA—Deputy Administrator; Directors, FAA Regions and Centers.

d. Although the delegations of authority are expressed above in terms of positions, the authority is personal and is vested only in the individual occupying the position. The authority may not be exercised "by direction of" a designated official. The formal appointment or assignment of an individual to one of the identified positions or a designation in writing to act in the absence of one of these officials, however, conveys the authority to originally classify the information.

2-9. Duration of Original Classification

a. At the time of original classification, eact DOT original classification authority shall set a date or event for automatic declassification. This date or event shall be no later than six (6) years after the original classification.

b. Within the DOT, only the Secretary of Transportation may classify information for more than the six-year period. In such cases a declassification date or event, or a date for review, shall be set. This date or event shall be as early as national security permits and shall be no more than twenty (20) years after the original classification. If a DOT classification authority, other than the Secretary, originally classifies information and believes the classification period needs to be extended beyond six years, a written justification should be forwarded through the OST Director of Investigations and Security for a decision by the Secretary.

2-10. *Classification Guides.* A classification guide shall be prepared for all original classification determinations made by a DOT official whenever it is anticipated that other elements of the department may produce documents which derive their classification from the original determination or whenever the portion markings are not considered specific enough to clearly identify the classified information. All classification guides shall be coordinated with the appropriate headquarters security element prior to issuance. For purposes of this paragraph, DD Forms 254, "Contract Security Classification Specification", are not considered classification guides. See Chapter XV for information on the DD 254.

The classification guide may be in any format which serves the purpose and shall be unclassified if at all possible. As a minimum, each classification guide will include the following:

a. Identify the information to be protected, using terms necessary to insure that the information to be protected can be readily and uniformly identified.

b. State which of the classification designations (SECRET or CONFIDENTIAL) apply to the identified information. No one in the DOT may classify information at the TOP SECRET level.

c. State the duration of classification for each item of information in terms of a period of time or a future event. If the duration of time is to exceed six years, see paragraph 2-9.

d. Each classification guide shall be approved personally and in writing by an official with original classification authority and the identity of the official shall be shown on the guide.

e. The classification guide shall be issued to any office expected to have a need for it with a copy provided to the OST Director of Investigations and Security.

2-11. Identification and Marking for Originally Classified Material

a. At the time of original classification, each document or other material containing classified information shall be marked to indicate that a classification determination has been made. By this means, persons who receive the material will know that the material requires protection, the degree of protection, and for how long the protection is needed. Each original classification shall be marked to show the following:

(1) A "Classified by" line to show the identity of the original classification authority unless this official is also the signer or approver of the document.

(2) The date or origin.

(3) The office of origin.

(4) The overall classification of the document.

(5) The declassification date or event or the date for review for declassification.

(6) Documents classified for more than six years shall also be marked with the identity of the classification authority who authorized the extension of classification and the reason for the extension.

(7) If applicable, the date of any downgrading action to be taken.

(8) The level of classification of each classified portion (chapter, section, page, paragraph, subparagraphs, subject or title, appendices, annexes, enclosures, etc.) and those portions which are unclassified.

b. Chapter IV should be consulted for detailed marking instructions and samples.

2-12. Derivative Classification

a. Derivative classification means a determination that information is in substance the same as other information that is currently classified, and a designation of the level of classification.

b. Derivative classification is a responsibility of those who incorporate, paraphrase, restate or generate in new form information that is already classified. Derivative classification also flows from complying with classification decisions set forth in a classification guide or as otherwise instructed by an authorized classifier.

c. Typically, derivative classification arises when a new document is produced in response to or as a reaction to another classified document. For example, a classified operations or contingency plan produced by another agency may require actions to be taken by DOT in support of the operation. A DOT-produced document implementing the basic plan would be created. This, in turn, could generate the production of additional documents at both headquarters and field elements. Although the DOT documents would contain information which would be new and in addition to that in the basic

plan, the classification of this information, if appropriate and warranted, would be based upon and derived from the basic plan. Similarly, the future declassification of the DOT documents would be determined by the declassification decision made by the original classification authority who classified the basic plan or source document.

d. As noted in paragraph 2-7, derivative classification also requires that classification judgments be made. In this instance, the judgment is whether the newly produced document actually contains information which the original classification authority of the source material considers to be classified. Paragraph marking of the source material aids significantly in making derivative determinations.

e. It is essential that officials preparing material related to classified source documents respect and comply with the classification decisions reflected in source material or classification guides. In some instances, however, it is possible to produce a document related to a classified source which is responsive and effective but which does not contain information warranting classification. A conscientious effort should be made meet this objective or, alternatively, to produce a document which can be classified at a lower designation than the overall classification of the source material.

2-13. Identification and Marking for Derivatively Classified Material

a. Officials who produce material which is subject to derivative classification shall assure that the information is properly classified, that the material is appropriately marked, and that the required security review, paragraph 2-17 has been accomplished.

b. Derivatively classified documents shall be marked to show the classification of each classified portion (chapter, section, page, paragraph, subparagraph, subject or title, appendixes, annexes, enclosure, etc.) and those portions which are unclassified.

c. Derivatively classified material shall show the date for declassification or review which appears on the source material. This same date shall be shown on each succeeding generation of derivatively classified documents. If the classification is derived from more than one source, the date for declassification or review applicable to the new material shall be the date which will retain the classification the longest.

d. Any additional markings which appear on the source material, such as Restricted Data or Formerly Restricted Data, or limitations on dissemination shall be shown on derivatively classified material.

e. Chapter IV should be consulted for detailed marking instructions and samples.

2-14. *Challenges to Classification.* If holders of classified information have substantial reason to believe that the information is classified improperly or unnecessarily or that an overly restrictive period for continued classification has been assigned, they are encouraged to contact the appropriate security element or the classifier of the information in an effort to bring about corrections if appropriate. The challenger's anonymity will be preserved if so requested. Challenges made under the provisions of this paragraph and paragraph 3-10, Mandatory Review, must include sufficient description of the information or document being challenged to permit identification with reasonable effort and must include the reason for the challenge. Challenges received must be acted on within thirty days and the challenger notified of any changes made or the reason no change was made.

2-15. *Compilations.* Where the use of classification higher than that which applies to any of its components is required to protect a compilation of information in a document, or where the individual parts of a compilation are unclassified but their total contents or their association is classified, mark the overall classification at the top and bottom of the front and back covers and the first page. The reason for classifying the compilation shall be included on the document or in its text. Normally a compilation of unclassified items shall not be classified. In rare instances, however, classification may be required if the compilation provides an added factor which in itself warrants classification. Classification on this basis shall be used sparingly.

2-16. Notification of Changes in Classification

a. Whenever a change in classification or duration of classification is determined by appropriate authority, other than changes predetermined to occur automatically, the authority making the determination shall promptly cause all known addressees to whom the information was disseminated to be notified of the change, any unusual action to be taken, the authority for the change, and the effective date. When so notified, holders of the affected material shall, in turn, notify all known addressees to whom they may have disseminated the information.

b. All affected material shall be promptly remarked to indicate the change, the authority for the action, date of the action, and identity of the person taking the action. Accountability records will be amended if appropriate.

c. In addition, material which was initially assigned a classification based upon information thus changed shall be reviewed immediately to determine if that material is affected by the changes in the source material. If so, actions prescribed in a. and b. above shall be taken.

2-17. Classification Review of DOT Produced Material

a. All classified material produced by DOT, whether original classification or derivative classification is involved, is subject to a classification review by appropriate security personnel. The material shall be reviewed to determine whether or not it contains classified information and if classified information is contained in the material, the review shall insure that:

(1) The appropriate classification designation is assigned,

(2) The downgrading/declassification markings are appropriate,

(3) The proper markings are affixed to the overall document, to titles and subjects, and to individual pages and paragraphs,

(4) The classifier, on original classification actions, is authorized to make the determination.

b. All classified documents, excluding messages, produced within DOT shall be reviewed by security personnel concerned prior to its release from the originating activity or when such material produced by a subordinate element is received into the activity.

c. Exception to the pre-release security review is authorized for field activities which produce only a minimal number of classified documents and which do not have resident security personnel at the location; provided that the annual security inspection of the activity shall include appropriate review of all classified documents produced since the last prior inspection.

2-18. Accountability of Classifiers

DOT officials who originally classify information or officials who make derivative classification determinations shall be held accountable for the propriety of their determinations. They shall maintain records which adequately support their determinations or by which the chain of classification can be traced to an original authority should an occasion demand such action. These records shall be maintained for the lifetime of the produced material. In

each instance of original classification, a complete copy of the document shall be forwarded immediately to the OST Director of Investigations and Security.

a. Original classification determinations shall include, with the record copy, a justification for the classification of the information. When other elements may produce documents which require classification because of the original classification determination, and a classification guide would facilitate applying the classification, the classifying official concerned shall arrange for development of a classification guide to be appropriately disseminated.

b. Derivative classification determinations shall include, with the record copy, a notation to show the document upon which the classification is based, or shall cite specific applicable provisions of a published classification guide. When more than one source document is involved, a listing of all sources shall be maintained with the record copy and a copy of this listing shall be furnished to the security control point.

2-19. Classified Material Transferred to DOT

a. Classified material officially transferred to DOT pursuant to statute of Executive Order in conjunction with a transfer of function, and not merely for storage purposes, shall be considered to have been originated by DOT for the purpose of downgrading and declassification.

b. Classified material in the custody of DOT originated by a department or agency which has ceased to exist and whose functions and records were not officially transferred to another department shall be downgraded and declassified by DOT holders of the material in accordance with the provisions of this Order. If it appears that another department or agency may have an interest in the subject matter of the material from a classification standpoint, that department shall be advised of the nature of the material and the intention to downgrade or declassify. The notified department shall be allowed thirty days in which to express an objection, if it so desires, before action is taken. Difference of opinion which cannot be resolved locally shall be referred to the Departmental Security Review Committee which will consult with its counterpart committee for the respective department.

2-20. Classified Material Transferred to Record Centers

At the time classified records are being prepared for transfer to a records center or to the National Archives for storage or retirement, action shall be taken to assure that each document has been remarked to reflect the current classification status. Whenever practicable, documents shall be reviewed to determine whether they can be downgraded or declassified. If no changes are warranted, a notation that a classification review was conducted shall be shown on the document or on the Record Transmittal and Receipt Form SF-135. If the review results in changes, the provisions of 2-16 shall be followed.

Chapter III—Declassification and Downgrading

3-1. Discussion

a. Information which is properly classified at the time it is developed does not necessarily require protection indefinitely. Most classified information has diminishing significance to the national security as time passes and as technological or other developments occur.

b. The lack of attention to downgrading and declassification in the past has resulted in the accumulation and protection of large volumes of material which actually no longer require protection, or which require a lesser degree of protection than afforded. Although attempts to correct this condition have been made, emphasis is still needed in this area.

c. The salient downgrading/declassification features of E. O. 12065 are:

(1) Declassification of classified information shall be given emphasis comparable to that accorded classification. Classified information shall be declassified as early as national security considerations permit. Decisions concerning declassification shall be based on the loss of the information's sensitivity with the passage of time or on the occurrence of a declassification event,

(2) Classified material, with limited exceptions, shall be automatically declassified after six years,

(3) Classified material still classified 20 years after origination is declassified, except for foreign government information, and

(4) A Systematic Review for declassification is required.

3-2. Definitions

a. *Downgrade.* To determine that classified information requires a lesser degree of protection against unauthorized disclosure in the interest of national security than that currently assigned; e.g. Top Secret is downgraded to Secret; Secret is downgraded to Confidential. Material will be re-marked to reflect this determination.

b. *Declassify.* To determine that information no longer requires protection against unauthorized disclosure in the interest of national security. Material will be re-marked to reflect this determination, *e.g.*, Top Secret, Secret or Confidential material is re-marked as Unclassified.

3-3. Authority to Downgrade or Declassify

a. *Originally Classified Material.* Original classification authorities, a successor in capacity or a supervisory official of either, a higher authority, and the Departmental Security Review Committee, are authorized to downgrade or declassify information originally classified by DOT. In addition, the following headquarters security elements are authorized to downgrade or declassify information originally classified by an official within their respective organizational element and to resolve classification conflicts or doubts as to the appropriate classification of that information:

OST and DOT Administrations other than USCG and FAA—OST Office of Investigations and Security.
FAA—Office of Investigations and Security.
USCG—Intelligence and Security Division.

b. *Derivatively Classified Material.* Declassification authority designated above and the appropriate District or Regional security elements within the USCG and FAA are authorized to declassify or downgrade derivatively classified material when such action does not conflict with classification decisions evidenced by the source material or instructions from an original classification authority.

3-4. Marking New Material For Declassification or Downgrading

a. New material which derives its classification from information classified on or after December 1, 1978, shall be marked with the declassification date or event, or the date for review, assigned to the source document.

b. New material that derives its classification from information classified prior to December 1, 1978, shall be treated as follows:

(1) If the source material bears a declassification date or event 20 years or less from the date of origin, that date or event shall be carried forward on the new material.

(2) If the source material bears a declassification date or event beyond 20 years, or bears no declassification date or event, the new material shall be marked with a date for review for declassification at 20 years from the date of original classification of the source material. The date of the source document may be used to compute this date if the date of original classification is not known.

(3) If the source material bears a downgrading date or event, that date or event shall be carried forward on the new material.

3–5. Systematic Review for Declassification

a. Classified information constituting permanently valuable records of the Government, as defined by U.S.C. 2103, and information in the possession and control of the Archivist of the United States, shall be systematically reviewed for declassification by the Archivist as it becomes 20 years old. In this review, the Archivist will separate and keep protected only such DOT produced material as is specifically identified by the Secretary as requiring protection. A determination that continued classification is warranted may be made only by the Secretary. When classification is extended beyond 20 years, a date no more than 10 years later shall be set for declassification or for the next review. Subsequent reviews for declassification shall be set at no more than 10 year intervals. The documents shall be marked to reflect the date for declassification or review. The OST Director of Investigations and Security is designated as the liaison officer for the Department with the Archivist for this purpose.

b. The OST Director of Investigations and Security shall assure that guidelines for the systematic review of 20-year-old classified information under DOT jurisdiction are issued and maintained. Guidelines shall be prepared in consultation with the Archivist of the United States and shall be reviewed by the Information Security Oversight Office (ISOO). These guidelines shall state specific, limited categories of information which, because of its national security sensitivity, should not be declassified automatically but should be reviewed item-by-item to determine whether continued protection beyond 20 years is needed. All information not identified in these guidelines as requiring review and for which a prior automatic declassification date has not been established, shall be automatically declassified at the end of 20 years from the date of original classification. These guidelines shall be reviewed at least every two years and revised as necessary unless earlier review is requested by the Archivist of the United States.

3–6. Notification to Holders

a. Whenever information is declassified by appropriate authority, other than changes pre-determined to occur automatically, the authority making the determination shall notify all known holders of the change.

b. This notification shall include the authority for the change (name and title) and the effective date of the change. Notification may be by general notice rather than personal notice so long as the general notice is designed to achieve the intended result.

3–7. Automatic Downgrading or Declassification. Material which is marked for automatic downgrading or declassification requires no further authority from the originator by any holder to re-mark the material. The marking itself conveys this authority.

3–8. Effect of Open Publication. The fact that information currently classified has been disseminated by a public medium of communication does not automatically mean that it has been declassified. Classification shall continue to be respected until advised to the contrary by the originating agency or higher authority. Questions as to the propriety of continued classification in these cases should be promptly borught to the attention of the originator. If the originator cannot be readily identifed, the matter should be referred to the OST Director of Investigations and Security.

3–9. Declassification of Presidential Papers. The Archivist of the United States has the authority to review and declassify information and material which has been classified by a President, his White House Staff or special committee or commission appointed by him and which the Archivist has in his custody at any archival depository, including a Presidential Library. Such declassification shall only be undertaken in accord with: (i) The terms of the donor's deed or gift, (ii) consultations with the Departments having a primary subject-matter interest, and (iii) the provisions of this chapter with respect to material of concern to DOT.

3–10. Mandatory Review for Declassification

a. E. O. 12065 requires that procedures be established to handle requests by a member of the public, by a government employee, or by an agency, to declassify and release information. In order to be acted upon, a requests needs to describe the information with sufficient particularity to permit the record to be identified and located. Requests for declassification under this Mandatory Review provision shall be acted upon within 60 days. aFter review, the record or any reasonably segregable portion thereof that no longer is in the interest of national security shall be declassified and released unless withholding is otherwise warranted under applicable law.

b. Requests for classified records made under the Freedom of Information Act, (FOIA), as amended, are processed differently than requests made under the Mandatory Review provision. See 3–12.

c. an agency in possession of a classified document may not, in response to a request for the document made under the Freedom of Information Act or the Mandatory Review provision of E. O. 12065, refuse to confirm the existence or non-existence of the document, unless the fact of its existence or non-existence would itself by classified.

3–11. Procedures for Submitting and Handling Requests for Mandatory Review.

a. The Director of Investigations and Security, M–50, Office of the Secretary of Transportation, 400 7th Street, S.W., Washington, D.C. 20590, is hereby designated as the official to whom a member of the public or another department or agency will submit a request for mandatory review of classified material produced by or under the primary cognizance of the Department of Transportation. Elements of the Department which may receive a request directly shall immediately notify the Director.

b. If the request involves material produced by or under the cognizance of the U.S. Coast Guard or the Federal Aviation Administration, the Director will forward the request to the headquarters security staff of the element for action. If the request involves material produced by other Departmental elements, the Director shall serve as the action officer.

c. Action offices shall:

(1) Immediately acknowledge receipt of the request and provide a copy of the correspondence to the Director. If a fee for search of records is involved, pursuant to the Department of Transportation regulations, 49 CFR Part 7, in implementation of the Freedom of Information Act, the requester shall be so notified,

(2) Conduct a security review which shall include consultation with the office which produced the material and with source authorities when the

classification, or exemption of material from automatic declassification, was based upon determinations by an original classifying authority; and

(3) Assure that the requester is notified of the determination within 60 days (or given an explanation as to why further time is necessary) and provide a copy of the notification to the OST Director of Investigations and security.

d. Whenever a request does not reasonably describe the records sought, the requester shall be notified that no further action can be taken without more specificity as to the records in question.

e. If the determination reached is that continued classification is required, the determination shall include a statement as to why the requested material cannot be declassified. The determination shall also advise the requester of the right to appeal. A requester who may wish to appeal a classification review decision, or who has not been notified of a decision after 60 days, should submit the appeal to the Chairman, Security Review Committee, M-1, Department of Transportation, 400 7th Street, SW., Washington, D.C. 20590.

f. If the determination reached is that continued classification is not required, the information shall be declassified and the material remarked. The action office will then refer the request to the Director of the Office of Public and Consumer Affairs or to the head of the operating element, as the case may be, responsible for the material, to determine if it is otherwise available for public release under Title 5, U.S.C. Section 552 (The Freedom of Information Act) and implementing regulations.

(1) If the material is releasable, the requester shall be advised that the material has been declassified and is available. If the request involves the furnishing of copies and a fee is to be included, the requester shall be so advised pursuant to 49 CFR 7.91 through 7.95.

(2) If the material is not releasable, the requester shall be advised that the material has been declassified but that the record is exempt from disclosure, pursuant to the Freedom of Information Act, and that the provisions of 49 CFR 7.81, which pertains to appeals, is applicable.

g. Upon receipt of an appeal from a classification review determination based upon continued classification, the Departmental Security Review Committee shall immediately acknowledge receipt and act on the matter within 30 days. With respect to information originally classified by or under the primary cognizance of DOT, the Committee, acting for the Secretary, has authority to over-rule previous determinations in whole or in part when, in its judgment, continued protection in the interest of national security is no longer required. When the classification of the DOT-produced material was based upon a classification determination made by another department or agency, the Security Review Committee (SRC) will immediately consult with its counterpart committee for that department.

(1) If it is determined that the DOT material requires continued classification, the requester will be so notified.

(2) If it is determined that the material no longer requires classification, it shall be declassified and remarked. The Committee shall refer the request to the Director of the Office of Public and Consumer Affairs, or the head of the operating element concerned, as the case may be, to determine if the material is otherwise available for public release under Title 5, U.S.C. Section 552, and implementing directives, and the provisions set forth in subparagraphs (1) and (2), paragraph f, above shall be followed. A copy of the response shall be provided to the Committee.

3-12. Procedures for Handling Requests Under the Freedom of Information Act Involving Classified Records

a. Amendments to the Freedom of Information Act, Title 5, U.S.C., Section 552, authorize withholding of records from public availability which are "(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive Order."

b. Persons who request records from an agency under the provisions of the Act, and whose requests are denied, may petition the courts to enjoin the agency from withholding the record and, in this event, the burden is on the agency to sustain its actions.

c. The Amendments also impose time limits for determinations on FOIA requests. A determination on an initial request must be made within 10 working days after receipt of the request. In case of an appeal to an initial denial, a determination must be made within 20 working days after receipt of the appeal. Except for unusual circumstances, failure to make a determination within the stated time limits means that a requester has exhausted the administrative remedies and may bring suit immediately.

d. To assure that FOIA requests involving classified records are subjected to a thorough classification review and response is made within the specified time limits, the procedures in paragraphs e. and f. shall apply.

e. Initial requests involving classified records.

(1) The office having responsibility to act upon a FOIA request shall consult immediately with the appropriate security element which shall conduct a classification review.

(2) If the record is declassified, the action officer shall be so advised and a determination of releasability shall be made without further reference to security considerations. A copy of the declassification decision shall be forwarded t the OST Director of Investigations and Security.

(3) If the record warrants continued classification, the action officer shall be advised prior to the expiration of the time limit. The action officer shall advise the requester of the denial following the provisions of 49 CFR 7.21, "Initial Determination".

(4) If the classification review cannot be completed within the statutory time limit, due to unusual circumstances, the security element will so advise the action officer. The action officer will arrange for an extension of time in accordance with the Act (5 U.S.C. 552 (a)(6)(B)) and 49 CFR 7.25, "Extension" and implementing Departmental regulations.

(5) A copy of the determination to deny based on classification of the record shall be forwarded immediately to:

(a) the OST Director of the Office of Public Affairs, the General Counsel, or to the head of an operating element, as the case may be; and

(b) the OST Director of Investigations and Security, through the appropriate headquarters security staff.

f. Receipt of an appeal for reconsideration of release of a classified record.

(1) The Departmental official receiving the appeal shall immediately refer the matter to the Departmental Security Review Committee which shall conduct a classification review. With respect to information originally classified by or under the primary cognizance of the Department, the Committee, acting for the Secretary, has authority to overrule previous determinations in whole or in part when, in its judgment, continued protection in the interest of national security is no longer required. When the classification of the record produced in the Department is based upon a classification determination made by another department or agency, the Security Review committee shall consult immediately with its counterpart

committee for that department. Before reaching a decision the Committee may consult with additional departments or committees as may be appropriate.

(2) If the Committee determines that the record is in fact properly classified pursuant to an Executive Order, the Committee shall so inform the head of the operating element concerned and the OST General Counsel. The head of the operating element concerned, or the General Counsel, as the case may be, shall issue a final denial to the requester.

(3) If the Committee determines that the record no longer requires classification, the head of the operating element concerned or the General Counsel, as the case may be, will be so informed. The head of the operating element or the General Counsel, as the case may be, shall determine if the material is otherwise available for public release and notify the requester.

(4) In its deliberations and notification to the head of the operating element or the General Counsel, as the case may be, the Committee shall determine, to the maximum extent possible, what portions of a requested record contains information properly classified and what unclassified portions may be reasonably segregated for the purpose of public availability.

(5) Actions upon appeal for reconsideration of requested records shall be completed within the prescribed time limits.

g. The OST Director of Investigations and Security is designated as the officer to whom another department or agency should submit a request for a classification review of classified material produced by or under the primary cognizance of the Department. If the reason for the review is based upon a request received by the other department or agency under the Freedom of Information Act, the director shall immediately inform the Chairman of the Security Review Committee who shall assure that action which is appropriate to the circumstances is taken. If the reason for the request for review is not based on the Freedom of Information Act, the director shall refer the matter to the operating element concerned or shall act directly on the matter. In either event, he shall assure that a proper and timely response is made.

3-13. *Public Availability of Declassified Information.* It is a fundamental policy of DOT to make information available to the public to the maximum extent permitted by law. Information which is declassified, for any reason, loses its protective status in the interest of national security. Accordingly, declassified information shall be handled in every respect on the same basis as all other unclassified information. Declassified information is subject to the Department of Transportation regulations (49 CFR Part 7) in implementation of the Freedom of Information Act and public information policies and procedures.

Chapter XI—Dissemination of Classified Information

11-1. *Discussion.* Information has no real value unless it is made available to those who can use it. This principle applies also to classified information. However, the dissemination of classified information is limited to those whose official duties require knowledge or possession thereof and further to those who will respect this limitation.

11-2. *Basic Provisions.*

a. Classified information may be released only to persons who have an official need for the information and only after they have been determined by designated authorities to be trustworthy for the classification level of information to be disclosed. For example, persons who are cleared at the SECRET level may not be given access to information at the TOP SECRET level. However, clearance for one level, i.e., TOP SECRET conveys authority for release of information classified at lower levels, i.e., SECRET or CONFIDENTIAL when a need for release exists. The mere fact that an individuals is employed by DOT or another department or agency of the government or is a member of the armed forces does not mean that he has been cleared for access to classified information.

b. A security clearance shall be administratively rescinded when an individual no longer requires access to classified information in the performance of official duties. Likewise, when an individual no longer needs access to a particular security classification category, the security clearance will be adjusted to the classification category still requied for the performance of his duties. In both instances, such action shall be taken without prejudice to the person's eligibility for security clearance should the need arise again. DOT Order 1630.2, PERSONNEL SECURITY PROGRAM, sets forth policies, standards, procedures and designated authorities for issuing and withdrawal of security clearances for DOT personnel.

c. Access to certain types of information may require additional authorization and controls.

d. Supervisors are responsible for controlling the dissemination of classified information received or generated in their offices to persons under their jurisdiction.

e. The responsibility for determining whether an individual has a need for specific items of classified information rests with the person or activity which has possession or control of the information and not with the prospective recipient.

f. Classified material originated by another department or agency and furnished to DOT shall not be further distributed outside DOT without the prior consent of the originating department or agency. This restriction does not apply to additional distribution within the DOT or to distribution to contractors who require the information in performance of DOT contracts.

g. Classified material shall not be released to an employee or other person for his private use (personal, commercial, or as background material) even though the individual may have been partly or solely responsible for producing the material.

h. Before approving a release of classified information to a person who serves in more than one capacity, e.g., a contractor employee who also acts as a private consultant, the releasing official shall determine in which capacity the intended recipient is acting and will follow the release and clearance procedures established for the appropriate category.

i. Personnel shall refuse access to classified information for which they lack either the required authorization or need-to-know.

j. Officials who disclose classified information verbally will advise the recipients of the classification of the information divulged.

k. Additional provisions for dissemination in connection with visiting are set forth in Chapter XII.

11-3. *Dissemination Within the Executive Branch.* Classified information originated by DOT activities may be disseminated to other departments and agencies of the Executive Branch as necessary for the conduct of official business.

11-4. *Dissemination Outside the Executive Branch.* Classified information shall not be disseminated outside the Executive Branch without the specific authorization of designated officials as indicated below. Classified material which is to be physically released to U.S. entities outside the Executive Branch shall be marked as prescribed by Chapter IV.

11-5. *To the Congress*

a. Provided other Departmental policies and procedures regarding

legislative affairs are met, classified information may be disseminated to the Congress when necessary in the interests of the national security and as authorized by the Secretary or the head of an operating administration. As used herein, the Congress includes members, committees, subcommittees, and staffs of members and committees.

b. DOT personnel who are to appear as witness before a Congressional Committee or who will meet with staff representatives shall obtain prior approval from an authority designated above for the disclosure of classified information which he anticipates will be requested.

c. A DOT witness who is requested to disclose classified information which he has not been authorized to release shall respectfully state that he does not have authority to testify on the matter but that he will endeavor to obtain authority or have the information furnished.

d. Witnesses shall request that classified testimony be given in Executive session only, that any record of such testimony be identified as classified and not appear in any document subject to public inspection or availability, and shall obtain the assurance of a committee representative that everyone present has a security clearance commensurate to the classification of the information to be released.

e. Offices which release classified documents are responsible to assure that they will be provided adequate physical safeguards.

f. Personal communications to Congress shall not include classified information. Classified information shall not be furnished for further release to a constituent.

g. Classified information to be disclosed shall be reviewed specifically to assure that the assigned classification is still valid.

11-6. *To Representatives of the General Accounting Office (GAO).* Properly cleared and identified representatives of the GAO may be granted access to DOT classified information at DOT activities when such information is relevant to the performance of their statutory responsibilities and duties in accordance with the following:

a. The GAO will give advance notice to the heads of DOT activities to be visited. Each announcement of a planned visit will include the purpose of the visit, names of the representatives, and if access to classified information is anticipated a certification as to the level of clearance of each representative.

b. The following GAO officials are authorized to certify security clearances: the Comptroller General, his Deputy, and Assistants; the General Counsel and Deputy General Counsel; the Director and Deputy Director, Office of Policy; the Directors, Deputy Directors, Associate Directors, and Assistant Directors of the following Divisions: General Government Resources and Economic Development, Resources and Economic Development, Manpower and Welfare, International, Transportation and Claims, Procurement and Systems Acquisition, Federal Personnel and Compensation, Logistics and Communications, Financial and General Management Studies; and Regional Managers.

c. GAO personnel can be identified by special credential cards issued by the Comptroller General. Each card is serially numbered and bears the photograph and signature of the authorized holder.

d. Requests for the following types of information shall be forwarded to the OST Director of Audits, who shall consult with the OST Director of Investigations and Security, for determination of whether or not the information is relevant to the performance of the GAO's statutory responsibilities and for authorization for release or access:

(1) TOP SECRET information;

(2) Other sensitive classified information falling in the general areas of tactical operations, intelligence and communications security;

(3) Classified information originated by another department or agency of the Executive Branch, including FBI reports.

e. When classified documents are furnished to GAO representatives, they shall be informed of the classified nature of the information and of the need for safeguarding it properly. In this connection, the Comptroller General has agreed to establish a security system at least equal to that prescribed by the Executive Branch.

11-7. *To the Government Printing Office (GPO).* Classified material, except TOP SECRET and similarly unique material, may be released to GPO plants, Washington and field, for reproduction when necessary as determined by DOT officials responsible for meeting printing and reproduction needs. The Public Printer has established policies and standards commensurate with those of the Executive Branch for the clearance of GPO personnel and for the safeguarding of classified information.

11-8. *To the Judiciary.* Every effort shall be taken to prevent the disclosure of classified information in proceedings before civil courts or a general courts-martial. If classified information becomes, or it appears that it might become, involved the matter will be referred immediately to the OST General Counsel. The General Counsel in consultation with the OST Director of Investigations and Security will furnish advice and guidance as appropriate to the circumstances of the given situation.

11-9. *To Foreign Governments, Foreign Nationals, and International Organizations.*

a. The release of classified information to foreign nationals (orally, visually or in documentary form) requires special attention and controls. This paragraph deals only with the protection and controlled release of classified information. Other Departmental directives in the area of international relations should be consulted also. The term FOREIGN NATIONAL includes a U.S. citizen acting as a representative of a foreign government or firm and is defined in Appendix 2—Item 23.

b. In rare instances, a DOT activity may wish to hire a foreign national as an employee or consultant in his capacity as a private individual. In this regard, the provisions of applicable directives and the Federal Personnel Manual will be followed. In addition, if access to classified information is involved, the activity or office shall submit a request to the security staff, headquarters of the respective operating administration or the OST Director of Investigations and Security, for authorization together with necessary personnel security forms. The following requirements shall be fulfilled:

(1) The request shall identify precisely the classified information intended for release. The security staff shall determine RELEASABILITY of the information in the manner described below as though the informmation were to be released to the government of the country of which the individual is national. Activities shall permit access only to that classified information for which authorization has been obtained. Procedural controls shall be established to effectively screen all information furnished to the foreign national employee.

(2) A full field investigation shall be completed and evaluated before access is granted. Interim authorizations are not permitted. Since investigation overseas will be involved, delays in completing the investigation should be anticipated. If it is not possible to obtain full investigation coverage, authorization shall be denied. Upon completion and evaluation a clearance, as defined by Appendix 2, Item 13, will not be issued. Rather, authorization will

be granted for access only to specifically identified information.

c. Except for the above, classified information as a matter of principle and policy is not made available to a foreign national as an individual but is disclosed to his government. The foreign national receives the information in his capacity as an official or representative of his government. By this means, the parent government accepts responsibility for the clearance of the individual and for the protection of the information.

(1) Policies governing the disclosure of classified military information to foreign governments are formulated by the National Military Information Disclosure Policy Committee (NDPC). Releases of certain other classified information, including Restricted Data, intelligence, and communications security information, are made pursuant to policies established by the agency or interagency entity having cognizance of the information proposed for release. Often the determination of cognizance is difficult and involved and, in many cases, more than one department or agency may need to be consulted for approval.

(2) As a prerequisite for release the department or agency proposing such release must make a clear determination that the benefits to the U.S. outweigh the disadvantages of disclosure. The cognizant department or agency must concur in this determination.

(3) The foreign government proposed as a recipient of U.S. classified information must officially assure this government that the information will be used only for official purposes, will be afforded protection at least equal to our requirements, will not be released to any other person or nation without our express permission, and corporate or proprietary rights (if any) in the information will be respected.

d. No release of classified information to a foreign national or foreign government may be made by a DOT activity without the express consent of the chief of the security staff of the headquarters of the appropriate operating administration or the OST Director of Investigations and Security.

e. Application for visits of foreign nationals to DOT activities wherein access to classified information may be involved, shall be made to the appropriate chief, security staff or OST Director of Investigations and Security, at least thirty days in advance of the proposed visit. In the case of a civilian or military representative of a foreign government application may be made by a civilian or military attaché of the mission of the country concerned. For all other foreign nationals (including U.S. citizen representing foreign interests), application shall be made by the Chief of Mission (ambassador, minister, etc.) of the country concerned. Applications shall contain the following information concerning the proposed visitor:

(1) Name in full, rank, title and position;

(2) Nationality, date and place of birth (in case of a civilian, furnish passport number);

(3) Employer or sponsor (if other than government making application);

(4) Name and address of installation(s) to be visited;

(5) Date, time and duration of proposed visit;

(6) Purpose of visit in detail, including estimated degree of access required;

(7) Secuirty clearance status of visitor with his own government;

(8) Where known and appropriate, names of individuals to be visited; and

(9) A certification that the visitor has been subjected to a military and political screening and does not constitute a security risk to the United States, that the visit and visitor are officially sponsored by his government which has officially cleared him to receive information on the stated purpose, that responsibility for the security of the information obtained is officially accepted by his government, that all information obtained will be used for official purposes only and will not be released to any other person or nation without the express consent of the U.S. Government, and that corporate or proprietary rights involved, patented, or not, will be respected and protected.

f. Requests for documentary release of classified information shall be processed generally in accordance with the procedures prescribed in 11-9c above. Documents contining classified information approved for release shall be delivered to the chief, security staff or OST Director of Investigations and Security, for onward transmission by means appropriate to the circumstances.

g. It is emphasized that these provisions apply to all situations wherein a foreign national may gain access to classified information in the custody of DOT. They apply to visits of DOT personnel to foreign countries, participants in exchange missions, conferences, meetings, symposia, etc. To avoid embarrassment, personnel should be careful to avoid firm invitations or commitments to foreign nationals which may involve access to classified information until the express consent for access is obtained. Other department or agency approval or sponsorship of a foreign national visit, sometimes referred to as a clearance, does not authorize access to classified information in the custody of DOT. Any proposed release of, or access to, classified information involving a foreign national, which is not covered in these provisions shall be submitted to the appropriate chief, security staff or OST Director of Investigations and security, for handling on a case-by-case basis.

11-10. To Historical Researchers.

a. Persons outside the Executive Branch who are engaged in historical research projects may have access to classified information provided that: (1) Access to the information will be clearly consistent with the interests of national security, and (2) the person to be granted access is trustworthy.

b. The provisions of this paragraph apply only to persons who are conducting historical research as private individuals or under private sponsorship and do not apply to research conducted under government contract or sponsorship. Further, the provisionss are applicable only to situations where the classified information concerned, or any part of it, was originated by DOT or by DOT contractors or where the information, if originated elsewhere, is in the sole custody of DOT. If any person requests access to material originated in another agency or to information under the exclusive jurisdiction of the National Archives and Records Service, General Services Administration, he should be referred to the other agency or to the National Archives and Records Service.

c. When a request for access to classified information for historical research is received, it will be referred to the appropriate local security office. The security office shall obtain from the applicant completed Standard Form 86 in triplicate, Investigation Data for Sensitive Position, and Standard Form 87, Fingerprint Chart; a statement in detail to justify access, including identification of the kind of information desired and the organization or organizations, if any, sponsoring the research; and a written statement (signed, dated, and witnessed) with respect to the following:

(1) That he will abide by regulations issued by DOT:

(a) To safeguard classified information; and

(b) To protect information which has been determined to be proprietary or privileged and is not eligible thereby for public dissemination.

(2) That he understands that any classified information which he receives affects the security of the U.S.

(3) That he acknowledges an obligation to safeguard classified information or privileged information of which he gains possession or knowledge as a result of his access to files of the Department.

(4) That he agrees not to reveal to any person or agency any classified information or privileged information obtained as a result of his access except as specifically authorized in writing by the DOT and further agrees that he shall not use the information for purposes other than that set forth in his application.

(5) That he agrees to authorize a review of his notes and manuscript for the sole purpose of determining that no classified information or material is contained therein.

(6) That he understands that failure to abide by conditions of this statement will constitute sufficient cause for canceling his access to classified information and for denying him any future access, and may subject him to criminal provisions of Federal law as referred to in this statement.

(7) That he is aware and fully understands that the provisions of Title 18, U.S. Code, Crimes and Criminal Procedures, and of the Internal Security Act of 1950, as amended. Title 50, U.S. Code, prescribe, under certain circumstances, criminal penalties for the unauthorized disclosure of information respecting the national security and for loss, destruction or compromise of such information.

(8) That this statement is made to the U.S. Government to enable it to exercise its responsibilities for the protection of information affecting the national security. That he understands that any material false statement which he makes knowingly and willfully will subject him to the penalties of Title 18, U.S. Code, Section 1001.

d. The security office shall process the forms in the same manner as specified for a preappointment NAC for a critical-sensitive position. Upon receipt of the completed NAC, the security office, if warranted, may determine that access by the applicant to the information will be clearly consistent with the interests of national security and the person to be granted access is trustworthy. If deemed necessary, before making its determination, the office may conduct or request further investigation. Before access is denied in any case, the matter will be referred through channels to the OST Director of Investigations and Security, for review and submission to the Secretary for final denial.

e. If access to TOP SECRET, intelligence or communications security information is involved a full field investigation is required. However, this investigation shall not be requested until the matter has been referred through channels to the OST Director of Investigations and Security for determination as to adequacy of the justification and the consent of other agencies as required.

f. When it is indicated that an applicant's research may extend to material originating in the records of another agency, approval must be obtained from the other agency prior to the grant of access.

g. Approvals for access shall be valid for the duration of the current research project but not longer than two years from the date of issuance, unless renewed. If a subsequent request for similar access is made by the individual within one year from the date of completion of the current project, access may again be granted without obtaining a new NAC. If more than one year has elapsed, a new NAC must be obtained. The local security office shall promptly advise its security staff, headquarters, of all approvals of access granted under these provisions.

h. An applicant should be given access only to that classified information which is directly pertinent to his approved project. He may review files or records containing classified information only in offices under the control of DOT. Procedures should be established to identify classified material to which he is given access. He should be briefed on local procedures established to prevent unauthorized access to the classified material while in the custody, for the return of the material for secure storage at the end of the daily working period, and for the control of his notes until they have been reviewed. In addition to the security review of the applicant's manuscript, the manuscript should be reviewed by appropriate offices to assure that it is technically accurate insofar as material obtained from the Department is concerned and is consistent with the Department's public release policies.

11-11. *To Former Presidential Appointees.* Persons who previously occupied policy-making positions to which they were appointed by the President may be granted access to classified information or material which they originated, reviewed, signed, or received while in public office, provided that:

a. It is determined that such access is clearly consistent with the interests of national security; and

b. The person agrees to safeguard the information, to authorize a review of his notes to assure that classified information is not contained therein, and that the classified information will not be further disseminated or published.

11-12. *To Contractors.* Classified information may be disclosed to DOT contractors, subcontractors, bidders, and grantees, and to contractors of other Government agencies, provided access to the information is necessary to the performance of the contract and required security clearances have been issued (see Chapter XII).

11-13. *To National Defense Executive Reservists (NDER's).* For the purposes of dissemination, members of the DOT NDER program are considered to be in the same category as employees. Classified information may be disclosed to DOT NDER's for which they have a need provided clearances have been issued pursuant to the provisions of DOT Order 1630.2, PERSONNEL SECURITY PROGRAM. However, classified material shall not be physically released to the custody of NDER's except upon request to the Director of Emergency Transportation, RSPA, and in accordance with procedures established by the latter after consultation with the OST Director of Investigations and Security.

11-14. *To Reserve Military Personnel for Training and to Retired and Inactive Status Military Personnel.* The Commandant, U.S. Coast Guard, shall establish policies and procedures for the dissemination of classified information to reserve, retired, and inactive status personnel. Releases to retired and inactive status personnel shall be on a selective basis, limited to those persons and to that information deemed warranted in the furtherance of the USCG or overall Departmental mission. Dissemination shall be orally or visually as distinguished from the physical release of documentary material. Classified information to be used in training courses for reserve personnel shall be screened and justified.

11-15. *To Others.* Proposed releases of classified information to persons not categorized above shall be referred to the security staff, headquarters of the respective operating administration or OST Director of Investigations and Security for approval and determination of limitations on release, if any, and measures necessary to assure the trustworthiness of the proposed recipient. The security element shall be consulted before any commitment to or understanding with the individual or entity has been made.

11-16. *Dissemination Through Meetings.*

a. DOT activities which host or convene a classified conference, symposium, seminar, exhibit, or

scientific and technical gathering (hereinafter referred to as a meeting) shall assure that security measures, appropriate to the circumstances, are taken. Requirements include, but are not limited to, the following:

(1) All persons attending the meeting shall be properly authorized and have a need for the information. In this regard, all attendees may not have a need for all of the information to be presented, particularly at a meeting covering a wide range of topics. In such instances, the agenda should be drawn and the meeting conducted in a manner to provide for selective attendance.

(2) Attendees shall be positively identified before being admitted to the meeting room.

(3) Persons who present classified information shall be advised of any limitations on their presentations which may be necessary because of the level of clearance or need-to-know of certain members of the audience. The speaker is responsible also for seeking such guidance and for keeping his disclosures within the prescribed limits.

(4) Notes, minutes, summaries, recordings, proceedings, reports, etc., on the classified portions of the meeting shall be safeguarded and controlled throughout the duration of the meeting. Such material, as appropriate, shall be forwarded to attendees by secure means at the conclusion of the meeting rather than being handcarried by them from the meeting site (except for local attendees).

(5) Physical and technical security controls shall be established as appropriate to the classification and sensitivity of the information to be discussed. Because of the security hazards inherent in the use of any normally public meeting place for the presentation or discussion of classified information, classified meetings or classified sessions of a meeting shall, whenever possible, be held only on a U.S. Government installation or a cleared contractor facility: Exception to this provision may be approved by the appropriate security element.

[FR Doc. 80-15825 Filed 5-23-80; 8:45 am]
BILLING CODE 4910-62-M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 80-136]

Customhouse Broker License; Cancellation Without Prejudice of Customhouse Broker License 3027

Notice is hereby given that the Commissioner of Customs, on May 16, 1980 pursuant to section 641, Tariff Act of 1930, as amended (19 CFR 111.51(a)), upon the specific request of Edward Limperis, Assignee for the Benefit of the Creditors of Gallagher & Ascher Company, and Margaret A. Gillespie, President, Gallagher & Ascher Company, cancelled without prejudice corporate customhouse broker's license No. 3027 issued to it on May 10, 1957, for the Customs District of Chicago, Illinois. The Commissioner's decision is effective as of May 16, 1980.

William T. Archey,
Acting Commissioner of Customs.
May 16, 1980.

[FR Doc. 80-16012 Filed 5-23-80; 8:45 am]
BILLING CODE 4810-22-M

[T. D. 80-135]

Customhouse Broker License; Cancellation Without Prejudice of Customhouse Broker License 3281

Notice is hereby given that the Commissioner of Customs, on May 16, 1980, pursuant to section 641, Tariff Act of 1930, as amended (19 CFR 111.51(a)), upon the specific request of Mark M. Trilling, Elmwood Park, Illinois, cancelled without prejudice individual customhouse broker's license No. 3281 issued to him on November 16, 1960, for the Customs District of Chicago, Illinois. The Commissioner's decision is effective as of May 16, 1980.

William T. Archey,
Acting Commissioner of Customs.
May 16, 1980.

[FR Doc. 80-16013 Filed 5-23-80; 8:45 am]
BILLING CODE 4810-22-M

[T.D. 80-134]

Customhouse Broker License— Cancellation Without Prejudice of Customhouse Broker License 3761

Notice is hereby given that the Commissioner of Customs, on May 16, 1980, pursuant to section 641, Tariff Act of 1930, as amended (19 CFR 111.51(a)), upon the specific request of John A. Bartolomei, Chicago, Illinois, cancelled without prejudice individual customhouse broker's license No. 3761 issued to him on February 15, 1966, for the Customs District of Chicago, Illinois. The Commissioner's decision is effective as of May 16, 1980.

William T. Archey,
Acting Commissioner of Customs.
May 16, 1980.

[FR Doc. 80-16014 Filed 5-23-80; 8:45 am]
BILLING CODE 4810-22-M

Office of the Secretary

[Department Circular; Public Debt Series— No. 18-80]

Treasury Notes of August 15, 1985; Series E-1985

May 22, 1980.

1. Invitation for Tenders

1.1. The Secretary of the Treasury, under the authority of the Second Liberty Bond Act, as amended, invites tenders for approximately $3,000,000,000 of United States securities, designated Treasury Notes of August 15, 1985, Series E-1985 (CUSIP No. 912827 KT 8). The securities will be sold at auction with bidding on the basis of yield. Payment will be required at the price equivalent of the bid yield of each accepted tender. The interest rate on the securities and the price equivalent of each accepted bid will be determined in the manner described below. Additional amounts of these securities may be issued at the average price to Federal Reserve Banks, as agents for foreign and international monetary authorities.

2. Description of Securities

2.1. The securities will be dated June 3, 1980, and will bear interest from that date, payable on a semiannual basis on February 15, 1981, and each subsequent 6 months on August 15 and February 15, until the principal becomes payable. They will mature August 15, 1985, and will not be subject to call for redemption prior to maturity.

2.2. The income derived from the securities is subject to all taxes imposed under the Internal Revenue Code of 1954. The securities are subject to estate, inheritance, gift or other excise taxes, whether Federal or State, but are exempt from all taxation now or hereafter imposed on the principal or interest thereof by any State, any possession of the United States, or any local taxing authority.

2.3. The securities will be acceptable to secure deposits of public monies. They will not be acceptable in payment of taxes.

2.4. Bearer securities with interest coupons attached, and securities registered as to principal and interest, will be issued in denominations of $1,000, $5,000, $10,000, $100,000, and $1,000,000. Book-entry securities will be available to eligible bidders in multiples of those amounts. Interchanges of securities of different denominations and of coupon, registered and book-entry securities, and the transfer of registered securities will be permitted.

2.5. The Department of the Treasury's general regulations governing

United States securities apply to the securities offered in this circular. These general regulations include those currently in effect, as well as those that may be issued at a later date.

3. Sale Procedures

3.1. Tenders will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, D.C. 20226, up to 1:30 p.m., Eastern Daylight Saving time, Wednesday, May 28, 1980. Noncompetitive tenders as defined below will be considered timely if postmarked no later than Tuesday, May 27, 1980.

3.2. Each tender must state the face amount of securities bid for. The minimum bid is $1.000 and larger bids must be in multiples of that amount. Competitive tenders must also show the yield desired, expressed in terms of an annual yield with two decimals, e.g., 7.11%. Common fractions may not be used. Noncompetitive tenders must show the term "noncompetitive" on the tender form in lieu of a specified yield. No bidder may submit more than one noncompetitive tender and the amount may not exceed $1.000,000,000.

3.3. All bidders must certify that they have not made and will not make any agreements for the sale or purchase of any securities of this issue prior to the deadline established in Section 3.1. for receipt of tenders. Those authorized to submit tenders for the account of customers will be required to certify that such tenders are submitted under the same conditions, agreements, and certifications as tenders submitted directly by bidders for their own account.

3.4. Commercial banks, which for this purpose are defined as banks accepting demand deposits, and primary dealers, which for this purpose are defined as dealers who make primary markets in Government securities and report daily to the Federal Reserve Bank of New York their positions in and borrowings on such securities, may submit tenders for account of customers if the names of the customers and the amount for each customer are furnished. Others are only permitted to submit tenders for their own account.

3.5. Tenders will be received without deposit for their own account from commercial banks and other banking institutions; primary dealers, as defined above; Federally-insured savings and loan associations; States, and their political subdivisions or instrumentalities; public pension and retirement and other public funds; international organizations in which the United States holds membership; foreign central banks and foreign states; Federal Reserve Banks; and Government accounts. Tenders from others must be accompanied by full payment for the amount of securities applied for (in the form of cash, maturing Treasury securities or readily collectible checks), or by a payment guarantee of 5 percent of the face amount applied for, from a commercial bank or a primary dealer.

3.6. Immediately after the closing hour, tenders will be opened, followed by a public announcement of the amount and yield range of accepted bids. Subject to the reservations expressed in Section 4, noncompetitive tenders will be accepted in full, and then competitive tenders will be accepted, starting with those at the lowest yields, through successively higher yields to the extent required to attain the amount offered. Tenders at the highest accepted yield will be prorated if necessary. After the determination is made as to which tenders are accepted, a coupon rate will be established, on the basis of a ⅛ of one percent increment, which results in an equivalent average accepted price close to 100.000 and a lowest accepted price above the original issue discount limit of 98.750. That rate of interest will be paid on all of the securities. Based on such interest rate, the price on each competitive tender allotted will be determined and each successful competitive bidder will be required to pay the price equivalent to the yield bid. Those submitting noncompetitive tenders will pay the price equivalent to the weighted average yield of accepted competitive tenders. Price calculations will be carried to three decimal places on the basis of price per hundred, e.g., 99.923, and the determinations of the Secretary of the Treasury shall be final. If the amount of noncompetitive tenders received would absorb all or most of the offering, competitive tenders will be accepted in an amount sufficient to provide a fair determination of the yield. Tenders received from Government accounts and Federal Reserve Banks will be accepted at the price equivalent to the weighted average yield of accepted competitive tenders.

3.7. Competitive bidders will be advised of the acceptance or rejection of their tenders. Those submitting noncompetitive tenders will only be notified if the tender is not accepted in full, or when the price is over par.

4. Reservations

4.1. The Secretary of the Treasury expressly reserves the right to accept or reject any or all tenders in whole or in part, to allot more or less than the amount of securities specified in Section 1, and to make different percentage allotments to various classes of applicants when the Secretary considers it in the public interest. The Secretary's action under this Section is final.

5. Payment and Delivery

5.1. Settlement for allotted securities must be made at the Federal Reserve Bank or Branch or at the Bureau of the Public Debt, wherever the tender was submitted. Settlement on securities allotted to institutional investors and to others whose tenders are accompanied by a payment guarantee as provided in Section 3.5., must be made or completed on or before Tuesday, June 3, 1980. Payment in full must accompany tenders submitted by all other investors. Payment must be in cash; in other funds immediately available to the Treasury; in Treasury bills, notes or bonds (with all coupons detached) maturing on or before the settlement date but which are not overdue as defined in the general regulations governing United States securites; or by check drawn to the order of the institution to which the tender was submitted, which must be received from institutional investors no later than Friday, May 30, 1980. When payment has been submitted with the tender and the purchase price of allotted securities is over par, settlement for the premium must be completed timely, as specified in the preceding sentence. When payment has been submitted with the tender and the purchase price is under par, the discount will be remitted to the bidder. Payment will not be considered complete where registered securities are requested if the appropriate identifying number as required on tax returns and other documents submitted to the Internal Revenue Service (an individual's social security number or an employer identification number) is not furnished. When payment is made in securities, a cash adjustment will be made to or required of the bidder for any difference between the face amount of securities presented and the amount payable on the securities allotted.

5.2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the face amount of securities allotted, shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5.3. Registered securities tendered in payment for allotted securities are not required to be assigned if the new securities are to be registered in the same names and forms as appear in the registrations or assignments of the securities surrendered. When the new securities are to be registered in names

and forms different from those in the inscriptions or assignments of the securities presented, the assignment should be to "The Secretary of the Treasury for (securities offered by this circular) in the name of (name and taxpayer identifying number)." If new securities in coupon form are desired, the assignment should be to "The Secretary of the Treasury for coupon (securities offered by this circular) to be delivered to (name and address)." Specific instructions for the issuance and delivery of the new securities, signed by the owner or authorized representative, must accompany the securities presented. Securities tendered in payment should be surrendered to the Federal Reserve Bank or Branch or to the Bureau of the Public Debt, Washington, D.C. 20226. The securities must be delivered at the expense and risk of the holder.

5.4 If bearer securities are not ready for delivery on the settlement date, purchasers may elect to receive interim certificates. These certificates shall be issued in bearer form and shall be exchangeable for definitive securities of this issue, when such securities are available, at any Federal Reserve Bank or Branch or at the Bureau of the Public Debt, Washington, D.C. 20226. The interim certificates must be returned at the risk and expense of the holder.

5.5. Delivery of securities in registered form will be made after the requested form of registration has been validated, the registered interest account has been established, and the securities have been inscribed.

6. General Provisions

6.1. As fiscal agents of the United States, Federal Reserve Banks are authorized and requested to receive tenders, to make attotments as directed by the Secretary of the Treasury, to issue such notices as may be necessary, to receive payment for and make delivery of securities on full-paid allotments, and to issue interim certificates pending delivery of the definitive securities.

6.2. The Secretary of the Treasury may at any time issue supplemental or amendatory rules and regulations governing the offering. Public announcement of such changes will be promptly provided.

Paul H. Taylor,

Fiscal Assistant Secretary.

Supplementary Statement

The announcement set forth above does not meet the Department's criteria for significant regulations and, accordingly, may be published without compliance with the Departmental procedures applicable to such regulations.

[FR Doc. 80-16129 Filed 5-23-80; 8:45 am]
BILLING CODE 4810-40-M

VETERANS ADMINISTRATION

Performance Review Board

AGENCY: Veterans Administration.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of 5 U.S.C. 4314(c)(4), notice is hereby given of the names of the members of the Performance Review Boards in the Veterans Administration. This notice revises the entire list of members published in the Federal Register, vol. 44, p. 75259, dated December 19, 1979.

EFFECTIVE DATE: May 27, 1980.

FOR FURTHER INFORMATION CONTACT: K. Joyce Edwards, Office of Personnel (05A), Veterans Administration, 810 Vermont Avenue NW., Washington, D.C. 20420, (202-389-3423).

THE MEMBERS OF THE VA'S PERFORMANCE REVIEW BOARDS ARE:

VA Performance Review Board

Charles E. Clark, Assistant Administrator for Personnel
Maury S. Crallé, Associate Deputy Administrator
Robert D. Vaughn, Assistant Deputy Administrator
Donald L. Custis, M.D., Chief Medical Director
Dorothy L. Starbuck, Chief Benefits Director
Carl T. Noll, Chief Memorial Affairs Director
Guy H. McMichael III, General Counsel
William R. Martin, Assistant Administrator for Data Management and Telecommunications
Sydney J. Shuman, Chairman, Board of Veterans Appeals
Conrad Hoffman, Controller
Frank R. Hood, Assistant Administrator for Information Services
Raymond S. Blunt, Assistant Administrator for Planning and Program Evaluation
H. David Burge, Director, Office of Manpower Programs

Department of Medicine and Surgery, Performance Review Board

William R. Merchant, M.D., Associate Deputy Chief Medical Director
Mansell G. Piper, Executive Assistant to Chief Medical Director
Donald B. Thompson, Executive Assistant to Deputy Chief Medical Director
Paul E. Wisenbaugh, M.D., Deputy Associate Deputy Chief Medical Director for Operations
Charles V Yarbrough, Director, Management Support Staff
Carlton M. Smith, Director, Northeastern Region
Charles R. Paulk, Director, Mid-Atlantic Region
Dan G. Kadrovach, Director, Southeastern Region
James H. Caldwell, Jr., Director, Great Lakes Region
Thomas P. Mullon, Director, Mid-Western Region
John J. Peters, Jr., Director, Western Region

Department of Veterans Benefits Performance Review Board

John W. Hagan, Jr., Deputy Chief Benefits Director
John P. Travers, Field Director, Western Region
Jerome C. Peckarsky, Director, Compensation and Pension Service
James J. Cox, Director, Veterans Assistance Service
Albert W. Glass, Director, Loan Guaranty Service

Dated: May 20, 1980.

By direction of the Administrator:

Rufus H. Wilson,

Deputy Administrator.

[FR Doc. 80-15957 Filed 5-23-80; 8:45 am]
BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 45, No. 103
Tuesday, May 27, 1980

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS.

1

COMMODITY FUTURES TRADING COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 45, No. 97, Friday, May 16, 1980, p. 32475.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., May 22, 1980.

CHANGES IN THE MEETING: The meeting has been postponed until May 23, 1980, at 11:30 a.m.

[S-1032-80 Filed 5-22-80; 11:42 am]

BILLING CODE 6351-01-M

2

FEDERAL ENERGY REGULATORY COMMISSION.

May 21, 1980.

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: 10 a.m., May 28, 1980.

PLACE: 825 North Capitol Street, NE., Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kenneth F. Plumb, Secretary, telephone (202) 357-8400.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the division of public information.

Power Agenda—451st Meeting, May 28, 1980, Regular Meeting 10:00 a.m.

CAP-1. Project No. 2830, Town of Madison Electric Works Department; Project No. 2915, Madison Paper Industries.
CAP-2. Project No. 2817, Vigilante Electric Cooperative, Inc., Project No. 2853, Montana Department of Natural Resources and Conservation.
CAP-3. Docket Nos. ER80-168, ER80-183, ER80-195, ER80-201, ER80-223, and ER80-239, American Electric Power Service Corp., et. al.
CAP-4. Docket No. ER80-326, New England Power Co.
CAP-5. Docket No. ER80-206, Florida Power Corp.
CAP-6. Docket No. ER80-57, Gulf States Utilities Co.
CAP-7. Docket No. ER80-112, Upper Peninsula Power Co.

Miscellaneous Agenda—451st Meeting, May 28, 1980, Regular Meeting

CAM-1. Docket No. RA80-15, Dwyer Motors, Inc.

Gas Agenda—451st Meeting, May 28, 1980, Regular Meeting

CAG-1. Docket No. RP80-102, Southern Natural Gas Co.
CAG-2. Docket No. RP80-101, Texas Gas Transmission Corp.
CAG-3. Docket No. RP80-95, National Fuel Gas Supply Corp.
CAG-4. Docket No. RP80-98, Valley Gas Transmission, Inc.
CAG-5. Docket No. RP80-97, Tennessee, Gas Pipeline Co., A division of Tenneco.
CAG-6. Docket Nos. RP80-91 and RP80-93, Arkansas Louisiana Gas Co.
CAG-7. Docket No. RP80-94, Peoples Natural Gas Co.
CAG-8. Docket No. RP80-100, Michigan Wisconsin Pipe Line Co.
CAG-9. Docket No. TA80-2-22 (PGA80-3), Consolidated Gas Supply Corp.
CAG-10. Docket No. TA80-2-58 (PGA80-3 and IPR80-2), Texas Gas Pipe Line Corp.
CAG-11. Docket No. CP77-240, Transcontinental Gas Pipe line Corp.
CAG-12. Docket No. RP71-125, Natural Gas Pipeline Co. of America.
CAG-13. Docket Nos. AR61-2, AR69-1, et al., RP67-23, RP71-6 et al., G-11980, et al., and RP73-114, Tennessee Gas Pipeline Co.
CAG-14. Docket No. RP80-85, National Fuel Gas Supply corp.
CAG-15. Docket No. RP80-1, Hampshire Gas Co.
CAG-16. Docket No. RP80-3, Michigan Wisconsin Pipe Line Co.
CAG-17. Docket Nos. RP75-82 and SA79-30, Cities Service Gas co.
CAG-18. Docket No. CI78-1128 et al., Arkla Exploration Co. et al.; Docket No. CI80-206, Tenneco Oil Co; Docket No. G-4880 et al., Diamond Shamrock Corp.; Docket No. CI80-178, Mobil Oil Exploration and Producing Southeast Inc.; Docket No. CI78-944, Amoco Production Co.; Docket No. CI80-15, Amerada Hess Corp.; Docket No. CI79-206, Northwest Exploration Co.
CAG-19. Docket No. CI78-514, The Louisiana Land and Exploration Co.
CAG-20. Docket No. G-5716, Northern Natural Gas Producing Co.; Docket No. G-7642, Mobil Oil Corp.; Docket No. CI79-592, John R. Lebosquet; Docket No. CI80-232, Mapco Production Co.
CAG-21. FERC gas rate schedule No. 67, Marathon Oil Co.
CAG-22. Docket No. Docket No. CP78-535, Natural Gas Pipeline Co. of America, Sea Robin Pipeline Co. and United Gas Pipeline Co., Complainants v. Texaco, Inc., Tenneco Oil Co. a Division of Tenneco, Inc., and Tennessee Gas Pipeline Co., a Division of Tenneco Inc., Defendants.
CAG-23. Docket No. CP80-172, Great Lakes Gas Transmission co.
CAG-24. Docket No. CP80-272, Cities Service Gas Co.
CAG-25. Docket No. CP80-207, Northern Natural Gas Co., Southern Natural Gas Co. and United Gas Pipe Line Co.
CAG-26. Docket No. CP80-39, Natural Gas Pipeline Co. of America.
CAG-27. Docket No. CP78-123 et al., Northwest Alaskan Pipeline Co.; Docket No. CP79-56, Northwest Pipeline Corp.; Docket No. CP79-57, El Paso Natural Gas Co.; Docket No. CP79-58, Pacific Interstate Transmission Co.; Docket No. CP79-59, Northwest Alaskan Pipeline Co.; Docket No. CP79-60, Pacific Gas Transmission Co.; Docket No. CP79-170, Northwest Alaskan Pipeline Co.; Docket No. CP78-124, Northern Border Pipeline Co.

Power Agenda—451st Meeting, May 28, 1980, Regular Meeting

I. Licensed Project Matters

P-1. Project No. 2928, South Columbia Basin Irrigation District.

II. Electric Rate Matters

ER-1. Docket No. ER80-225, Delmarva Power & Light Co.
ER-2. Docket No. ER80-337, Southwestern Electric Power Co.
ER-3. Docket Nos. ER80-379 and ER80-380, Utah Power & Light Co.
ER-4. Docket Nos. ER78-229, et al., Indiana & Michigan Electric co. et al.
ER-5. Docket Nos. ER78-379, ER78-381, ER78-382, and ER78-383, Indiana & Michigan Electric Co.
ER-6. Docket No. ER76-530, Arizona Public Service Co.
ER-7. Docket No. ER77-277 (Phase 1), Pennsylvania Power Co.

Miscellaneous Agenda—451st Meeting, May 28, 1980, Regular Meeting

M-1. Reserved.

M-2. Reserved.
M-3. (A) Docket No. RM80-6, Pricing of pipeline and affiliate production under the Natural Gas Act; (B) Docket No. RM80-7, final rule governing the maximum lawful price for pipeline, distributor or affiliate production.
M-4. Docket No. RM80-11, Distributor access to outer Continental Shelf Gas.
M-5. Docket No. RM79-40, determination of alternative fuels for essential agricultural users.
M-6. (A) Docket No. RM80-47, final subpart K of part 271 regulations under the Natural Gas Policy Act of 1978; (B) Docket No. CI77-412, Phillips Petroleum Co.; (C) RM80-21, regulations under section 110 of the Natural Gas Policy Act of 1978.
M-7. Docket No. RM80-38, rule to provide incentive pricing for high-cost natural gas produced from wells drilled in deep waters.
M-8. Docket No. RM80-50, High cost gas production enhancement.
M-9. Docket No. RO79-9, Mobil Oil Corp.

Gas Agenda—451st Meeting, May 21, 1980, Regular Meeting

I. Pipeline Rate Matters

RP-1. Docket No. Docket No. RP79-23, Distrigas of Massachusetts Corp., Docket No. RP79-24, Distrigas Corp.
RP-2. Docket No. RP79-12 (extension), El Paso Natural Gas Co.

II. Producer Matters

CI-1. Docket No. RI79-21, Shell Oil Co

III. Pipeline Certificate Matters

CP-1. Docket No. CP80-283, Texas Eastern Transmission Corp.
CP-2. Docket No. CP75-81 and CP75-104, High Island Offshore System.
CP-3. Docket No. CP79-240, Seagull Pipeline Corp.
CP-4. Docket No. G-20584, Kansas-Nebraska Gas Co.
CP-5. Docket No. VP79-234, Algonquin Gas Transmission Co.; Docket No. CP79-338, Texas Eastern Transmission Corp.; Docket No. CP79-339, Texas Eastern Transmission Corp.; Docket No. CP79-368, Transcontinental Gas Pipe Line Corp.; Docket No. CP79-369, Transcontinental Gas Pipe Line Corp.; Docket No. CP78-256, Algonquin Gas Transmission Co.

Kenneth F. Plumb,

Secretary.

[S-1030-80 Filed 5-22-80; 11:00 am]

BILLING CODE 6450-85-M

3

FEDERAL HOME LOAN BANK BOARD.

TIME AND DATE: 9:30 a.m., May 29, 1980.

PLACE: 1700 G Street NW., amphitheater, second floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Marshall (202-377-6677).

MATTERS TO BE CONSIDERED:

Application for Bank Membership—Home Savings Bank, Boston, Mass.
Application for Bank Membership—City Savings Bank of Meriden, Meriden, Conn.
Application for Bank Membership—Andover Savings Bank, Andover, Mass.
Application for Bank Membership—Amherst Savings Bank, Amherst, Mass.
Application for Branch Office—First Federal Savings & Loan Association of Warren, Warren, Ohio.
Application for Branch Office—Rossville Federal Savings & Loan Association, Rossville, Ga.
Final Approval of Exact Location of Limited Facility—Biscayne Federal Savings & Loan Association, Miami, Fla.
Application for Satellite Office—Biscayne Federal Savings & Loan Association, Miami, Fla.
Preliminary Application to Convert to a Federal charter—Penn Savings & Loan Association, Newark, N.J.
Merger—Fillmore Savings & Loan Association, Buffalo, N.Y. into Buffalo Savings Bank, Buffalo, N.Y.
Pledge and Escrow Agreement.
Suspension and Prohibition from Participation in Association Affairs—First Federal Savings & Loan Association of Fall River, Fall River, Mass.

[S-1033-80 Filed 5-22-80; 2:57 pm]

BILLING CODE 6720-01-M

4

FEDERAL HOME LOAN MORTGAGE CORPORATION

TIME AND DATE: 1 p.m., May 29, 1980.

PLACE: 1700 G Street NW., amphitheather, Second floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Henry Judy (202-789-4734).

MATTERS TO BE CONSIDERED: Federal Home Loan Mortgage Corporation Pension Plan.

No. 350, May 22, 1980.

[S-1038-80 Filed 5-22-80; 3:56 pm]

BILLING CODE 6720-02-M

5

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION.

May 20, 1980.

TIME AND DATE: 10 a.m., May 28, 1980.

PLACE: Room 600, 1730 K Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following: 2. McCracken v. Valley Camp Coal Co., Docket No. WEVA 79-116-D. (Petition for Discretionary Review)

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen, 202-653-5632.

[S-1036-80 Filed 5-22-80; 2:57 p.m.]

BILLING CODE 6820-12-M

6

NATIONAL CREDIT UNION ADMINISTRATION.

TIME AND DATE: 9:30 a.m., Wednesday, May 28, 1980.

PLACE: Seventh floor board room, 1776 G Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Review of Central Liquidity Facility lending rate.
2. The collection and processing of semi-annual financial and statistical data from all federally-insured credit unions.
3. Report on actions taken under delegations of authority.
4. Applications for charters, amendments to charaters, bylaw amendments, mergers as may be pending at that time.

RECESS: 10:30 a.m.

TIME AND DATE: 10:45 a.m., Wednesday, May 28, 1980.

PLACE: Seventh floor board room, 1776 G Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Requests from federally insured credit unions for special assistance under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A).
2. Administrative actions under Sections 120 and 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A) and (10).
3. Administrative action under Section 207 of the Federal Credit Union Act. Closed pursuant to exemptions (7), (8), (9)(A) and (9)(B).
4. Insurance application of State chartered credit union. Closed pursuant to exemption (9)(A).
5. Mergers. Closed pursuant to exemptions (8) and (9)(A).
6. Field of membership conversion. Closed pursuant to exemptions (8) and (10).
7. NCUSIF recommended guidelines for internal practices. Closed pursuant to exemption (9)(B).
8. Personnel Action. Closed pursuant to exemption (6).

FOR MORE INFORMATION CONTACT: Rosemary Brady, Secretary of the Board, telephone (202) 357-1100.

[S-1029-80 Filed 5-22-80; 11:00 am]

BILLING CODE 7535-01-M

7

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: Wednesday, May 28, 1980.

PLACE: Room 550, 4350 East West Highway, Bethesda, Md.

STATUS: Open/closed.

MATTERS TO BE CONSIDERED:

10 a.m.

1. Discussion of Action Plan (approximately 2 hours, public meeting).

2 p.m.

1. Continuation of Discussion of Action Plan (approximately 2 hours, public meeting).
2. Discussion of OGC Document on Motion to Quash Subpoenas Issued by I&E (approximately ½ hour, closed—Exemption 10).

CONTACT PERSON FOR MORE INFORMATION: Walter Magee (202) 634–1410.

AUTOMATIC TELEPHONE ANSWERING SERVICE: (202) 634–1498.

Those planning to attend a meeting should reverify the status on the day of the meeting.

May 21, 1980.

Roger M. Tweed,

Office of the Secretary.

[S-1035-80 Filed 5-22-80; 2:57 pm]

BILLING CODE 7590-01-M

8

POSTAL SERVICE.
(Board of Governors)

Notice of Meeting

The Board of Governors of the United States Postal Service, pursuant to its Bylaws (39 CFR 7.5) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice that it intends to hold a meeting at 9 a.m. on Tuesday, June 3, 1980, in the Benjamin Franklin Room, 11th floor, Postal Service Headquarters, 475 L'Enfant Plaza, S.W., Washington, D.C. Except as indicated in the following paragraphs, the meeting is open to the public. The Board expects to discuss the matters stated on the Agenda which is set forth below. Requests for information about the meeting should be addressed to the Secretary of the Board, Louis A. Cox, at (202) 245–4632.

On May 6, 1980, the Board of Governors of the United States Postal Service voted to close to public observation portions of its meeting scheduled for June 3, 1980. Each of the members of the Board voted in favor of partially closing this meeting, which is expected to be attended by the following persons: Governors Wright, Hardesty, Allen, Camp, Ching and Sullivan; Postmaster General Bolger; Deputy Postmaster General Conway; Senior Assistant Postmaster General Finch; and Secretary of the Board Cox.

A portion of the meeting to be closed involves a discussion of certain individual personnel actions which may involve adjustments in the compensation of certain officers of the Postal Service.

The other portion of the meeting to be closed will consist of a continuation of the discussion by the Governors of the Opinion and Recommended Decision Upon Reconsideration of the Postal Rate Commission re Electronic Mail Classification Proposal, 1978 (Commission Docket No. MC78-3), dated April 8, 1980.

Agenda

1. Minutes of the Previous Meeting.
2. Remarks of the Postmaster General. (In keeping with its consistent practice, the Board's agenda provides this opportunity for the Postmaster General to inform the members of miscellaneous current developments concerning the Postal Service. He might report, for example, the appointment or assignment of a key official, or the effect on postal operations of unusual weather or a major strike in the transportation industry. Nothing that requires a decision by the Board is brought up under this item.)
3. Report of the Chief Postal Inspector. (Chief Postal Inspector Fletcher will report on the Postal Inspection Service.)
4. Review of Public Affairs and Communications Program. (Mr. Duka, Assistant Postmaster General, Public and Employee Communications Department, will report on developments in the communications area.)
5. Discussion of Personnel Actions. (The Board will discuss certain individual personnel actions. As stated above in the Notice of Meeting, this portion of the meeting will be closed to the public.)
6. Recommended Decision upon Reconsideration of the Electronic Mail Classification Proposal, 1978 (Commission Docket No. MC78-3). (The Governors will consider the above Recommended Decision of the Postal Rate Commission. As stated above in the Notice of Meeting, the part of the meeting that will be devoted to this matter will be closed to the public.)

Louis A. Cox,

Secretary.

[S-1034-80 Filed 5-22-80; 2:57 pm]

BILLING CODE 7710-12-M

9

SECURITIES AND EXCHANGE COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENTS: To be published.

STATUS: Closed meeting.

PLACE: Room 825, 500 North Capitol Street, Washington, D.C.

DATES PREVIOUSLY ANNOUNCED: Wednesday May 21, 1980.

CHANGES IN THE MEETING: Additional items. The following additional items will be considered at a closed meeting scheduled for Thursday, May 22, 1980, immediately following the 10 a.m. open meeting:

Formal order of investigation.
Institution of injunctive action.

Commissioners Loomis, Evans, Pollack, and Friedman determined that Commission business required the above changes and that no earlier notice thereof was possible.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Paul Lowenstein at (202) 272-2091.

May 21, 1980.

[S-1031-80 Filed 5-22-80; 11:42 am]

BILLING CODE 8010-01-M

Federal Register

Tuesday
May 27, 1980

Part II

Department of Health and Human Services

Food and Drug Administration

Anorectal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 346

[Docket No. 80N-0050]

Anorectal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions under which over-the-counter (OTC) anorectal drug products for the relief of symptoms associated with hemorrhoids and other anorectal disorders are generally recognized as safe and effective and not misbranded. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Hemorrhoidal Drug Products, is part of the ongoing review of OTC drug products conducted by the Food and Drug Administration (FDA).

DATES: Comments by August 25, 1980 and reply comments by September 24, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on January 24, 1978, a report of the Advisory Review Panel on OTC Hemorrhoidal Drug Products. Under § 330.10(a)(6) (21 CFR 330.10(a)(6)), the agency issues (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC anorectal drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditons excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of the FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members but does not necessarily reflect the agency's position on any particular matter contained in it. After reviewing all comments submitted in response to this proposal, FDA will issue a tentative final regulation in the Federal Register to establish a monograph for OTC anorectal drug products.

The agency recognizes that extensive changes will result in the marketing practices of anorectal drug products if the Panel's recommendations are fully implemented. For example, the Panel found that few clinical studies have been conducted in the anorectal area and recommended that studies be conducted in this area to reclassify Category III conditions to Category I. The Panel has also proposed final formulation testing for anorectal combination products.

The agency notes that the Panel's decision to place pramoxine hydrochloride in Category I was based primarily on data submitted by one manufacturer. Because the Panel based its conclusions on these data, and because it was concerned about the bioavailablity of final formulations of anorectal preparations, the Panel concluded that only pramoxine hydrochloride in these specific formulations can be generally recognized as safe and effective for OTC external use in anorectal drug products. The Panel's Category I recommendation was conditioned upon the disclosure of the exact formulation of each pramoxine hydrochloride-containing product. Subsequently, after adoption of the Panel's report, FDA contacted the manufacturer for permission to include the exact formulation in the proposed monograph. The manufacturer agreed by letter to permit the formulations to be disclosed in the monographs, but did not agree to disclosing the quantities of each ingredient. This letter has been included in OTC volume 120084. (See part I. paragraph D. below—Referenced OTC Volumes.) Accordingly, the monograph specifies only the quantity of pramoxine hydrochloride but not the quantities of the other ingredients in the formulations. The agency recognizes that the Panel's recommendation for pramoxine hydrochloride is unusual in that it has placed only two specific formulations in Category I. The agency invites comment on this approach and whether these formulations or any other formulation for pramoxine hydrochloride should be included in the final monograph.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), the Panel and FDA have held as confidential all information concerning OTC anorectal drug products submitted for consideration by the Advisory Review Panel. All the submitted information will be put on public display at the office of the Hearing Clerk, Food and Drug Administration, after June 19, 1980, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

Based upon the conclusions and recommendations of the Panel, FDA proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and are not misbranded (Category I), be effective 30 days after the date of publication of the final monograph in the Federal Register.

2. That the conditions excluded from the monograph because they would cause the drug to be not generally recognized as safe and effective or to be misbranded (Category II), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the Federal Register, regardless of whether further testing is undertaken to justify their future use.

3. That the status of Category III conditions after publication of a final order is the subject of the recent court decision in the case of *Cutler* v. *Kennedy*, 475 F Supp. 838 (D.D.C. 1979). In that case, the court held that "FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions* * * are exempted from enforcement action" (*Cutler, supra* at 856). The Court issued an order that declared the OTC drug regulations (21 CFR 330.10) unlawful to the extent that they authorize the

marketing of Category III drugs after a final monograph, and enjoined the FDA from implementing any portion of the regulations that authorizes such marketing. In the Federal Register of May 13, 1980 (45 FR 31422), FDA issued a proposal to revise the procedural regulations governing the review and classification of OTC drug products to delete the provision that authorizes the marketing of a Category III condition in an OTC drug product after a final monograph. The term Category III, however, may continue to be used prior to publication of a final monograph.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the Federal Register of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the Federal Register of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC anorectal drug products was issued in the Federal Register of April 26, 1973 (38 FR 10307).

The Commissioner appointed the following Panel to review the information submitted and to prepare a report under § 330.10(a) (1) and (5) on the safety, effectiveness, and labeling of those products: Claude Emerson Welch, M.D., Chairman, Leon Banov, Jr., M.D., Eugene A. Castiglia, M.D., Winston H. Gaskin, R.Ph., Jean Dace Golden, M.D., Thaddeus S. Grosicki, Ph.D., Judith Karen Jones, M.D., Ph.D.

The Panel was first convened on July 9, 1973 in an organizational meeting. Working meetings were held on September 6 and 7, October 7 and 8, December 8 and 9, 1973; February 3 and 4, March 9 and 10, May 12 and 13, August 3 and 4, September 21 and 22, November 1 and 2, December 13 and 14, 1974; January 31 and February 1, March 9 and 10, May 1, 2, and 3, June 30 and July 1, September 8 and 9, November 16 and 17, 1975; January 3 and 4, March 14 and 15, May 1 and 2, July 9 and 10, August 20 and 21, November 21, 22 and 23, December 20 and 21, 1976; January 22 and 23, February 20 and 21, April 29 and 30, August 25, 26, and 27, 1977; and January 22, 23, and 24, 1978. The minutes of the Panel meetings are on public display in the office of the Hearing Clerk (HFA–305), Food and Drug Administration (address above).

Two nonvoting liaison representatives served on the Panel. Allen J. Seeber, nominated by the Consumer Federation of America, served as the consumer liaison and Garrett Swenson, R.Ph., Esq., nominated by the Proprietary Association, served as the industry liaison until he resigned from the Panel in October 1974, and was followed by Hugh Miller, M.D., who was also nominated by the Proprietary Association. The following FDA employees also served: Samuel Jacques Sunnenblick, M.D., served as Executive Secretary until February 1974, and was followed by Clyde G. Oberlander, R.Ph.; Thomas DeCillis, R.Ph., served as Panel Administrator; Melvin Lessing, R.Ph., M.S., served as Drug Information Analyst until October 1973, and was followed by Lloyd Scott, R.Ph., who served until April 1974, and was followed by Gary P. Trosclair, R.Ph.

In addition to the Panel members and liaison representatives, the following individuals were given an opportunity to appear before the Panel to express their views either at their own or at the Panel's request: John Adriani, M.D., M. F. Bartlett, Ph.D., John Behrman, M.D., Robert G. Blank, Ph.D., Eric G. Comstock, M.D., I. Kelman Cohen, M.D., W. R. Darrow, M.D., R. M. Diener, D.V.M., Frank Engley, Ph.D., Arthur D. Flanagan, M.D., Jock L. Graeme, M.D., Richard A. Hopping, M.D., Thomas K. Hunt, M.D., Joseph L. Kanig, Ph.D., Ben Marr Lanman, M.D., Louis Lasagna, M.D., Myron Lover, Ph.D., James D. MacLowery, M.D., Howard I. Maibach, M.D., Juha Niinikoski, M.D., Ronald Okun, M.D., Alan Parks, M.D., Hans J. Rosenbach, R.Ph., Jay P. Sanford, M.D., T. Werner Schwarz, Ph.D., Garrett W. Swenson, Esq., Mark E. Thoman, M.D., Donald D. Trunkey, M.D., Jouni Uitto, M.D., Ph.D., Le Roy Van Dam, M.D., Alexander G. Vongries, M.D., James C. White, M.D., Bengt Zederfeldt, M.D.

No person who so requested was denied an opportunity to appear before the Panel.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent data and information submitted through January 24, 1978, in arriving at its conclusions and recommendations.

The charge to the Panel required the review of OTC hemorrhoidal ingredients. However, the Panel concluded early in its deliberations that the term "hemorrhoidal" was too restrictive because it narrowed the review to relief of symptoms due to only one type of anorectal disorder. Therefore, the Panel interpreted the charge to encompass not only relief of symptoms due to hemorrhoidal disease, but also relief of symptoms of disease in the perianal, anal canal, and/or the lower rectal area. The Panel recommends that the ingredients

reviewed in this document be referred to as "anorectal" ingredients as a more accurate designation of the area in which symptoms are being relieved. (See part I. paragraph C. below—Classification of Ingredients and part II. paragraph A.1. below—Introduction.)

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel's findings with respect to OTC anorectal drug products are set out in three categories:

Category I. Conditions under which OTC anorectal drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC anorectal drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

I. Submission of Data and Information

Pursuant to the notice published in the Federal Register of April 26, 1973 (38 FR 10307) requesting the submission of data and information on hemorrhoidal drugs, the following firms made submissions relating to the indicated products:

A. Submissions by Firms

Firm	Marketed products
Abbott Laboratories, North Chicago, IL 60064	Tronothane Hydrochloride 1% Topical Local Anesthetic Cream, Tronothane Hydrochloride 1% Topical Local Anesthetic Jelly
Astra Pharmaceutical Products, Inc., Worcester, MA 01606	Xylocaine Topical Anesthetic Ointment 2.5%.
Astro-Solar Laboratories, Wheatfield, IN 46392	Tengum
Bellwood Pharmaceutical Co., Philadelphia, PA 19151	Hemozone.
Bristol-Myers Co., New York, NY 10022	Pazo Hemorrhoid Ointment, Pazo Hemorrhoid Suppositories, Aerosol Medicated Anal Wipe Foam.
Chesebrough-Pond's, Inc., Trumbull, CT 06611	Vaseline Pure Petroleum Jelly
Ciba-Geigy Corp., Summit, NJ 07901	Nupercainal Anesthetic Ointment, Nupercainal Suppositories.
Combe, Inc., White Plains, NY 10601	Lanacane Creme
Dr Kade Pharmazeutsche, Fabrik GmbH, Berlin, Germany	Postensan Suppositones, Posterisan Ointment, Posterisan Combi-Package.
Fuller Laboratories, Inc., Eden Prairie, MN 55343	Tucks Cream, Tucks Medicated Pads, Tucks Ointment, Tucks Take-Alongs.
Merrell-National Laboratories, Cincinnati, OH 45215	Diothane Ointment.
Phenex Laboratones, Chicago, IL 60641	Phenex Rectal Suppositories.
Philips Roxane Labs., Inc., Columbus, OH 43216	Gentz Wipes.
Pitman-Moore, Indianapolis, IN 46268	Dyclonine Hydrochloride.
Quist Chemical Co., Niagara Falls, NY 14304	Quist Ointment.
Reed & Carnrick Pharmaceuticals, Kenilworth, N.J. 07033	Non-Steroid Proctofoam.
Resinol Chemical Co., Baltimore, MD 21201	Resinol Greaseless Cream, Resinol Ointment.
The Upjohn Co., Kalamazoo, MI 49001	Epinephricaine Rectal Ointment, Tanicaine Rectal Ointment, Tanicaine Rectal Suppositories.
Warner-Chilcott Laboratories, Morris Plains, NJ 07950	Anusol Hemorrhoidal Suppositories, Anusol Ointment.
Whitehall Laboratones, Inc., New York, NY 10017	Preparation H Hemorrhoidal Ointment, Preparation H Hemorrhoidal Suppositories.
Winthrop Laboratones, New York, NY 10016	PNS Rectal Suppositories, Pontocaine Cream, Pontocaine Ointment.
Wyeth Laboratones, Inc., Philadelphia, PA 19101	Protogel, Wyanoid Hemorrhoidal Ointment, Wyanoids Hemorrhoidal Suppositories.

In addition, the following firms or individuals made related submissions:

Firm	Marketed products
American Home Products Corp., New York, NY 10017	Supplemental Submissions on Skin Respiratory Factor (SRF).
Angle, Carol R., M.D., University of Nebraska Medical Center, Omaha, NE 68105.	Toxicity of Camphor.
Arnar-Stone Laboratories, Inc., Mount Prospect, IL 60056	Benzocaine.
Astra Pharmaceutical Products, Inc., Worcester, MA 01606	Supplement to Xylocaine Ointment.
Bristol-Myers Co., New York, NY 10022	Remarks on Combination Policy.
Chesebrough-Pond's Inc., Trumbull, CN 06611	Clinical Studies on Vaseline Petroleum Jelly.
Ciba-Geigy Corp., Summit, NJ 07901	Dibucaine, Acetone Sodium Bisulfite, Presence of Sensory Receptors Within Rectal Mucosa.
Combe, Inc., White Plains, NY 10604	Resorcinol, Irritation Studies on Lanocaine.
Dow Chemical Co., Indianapolis, IN 46268	Supplemental Submission on Dyclone Creme 1%.
Fuller Laboratones, Inc., Eden Prairie, MN 55343	Hamamelis Water.
Humphreys Pharmacal, Inc., Rutherford, NJ 07070	Hamamelis Water.
Merrell-National Laboratories, Cincinnati, OH 45215	Oxyquinoline Benzoate and Diperodon.
Meyer Laboratories, Inc., Fort Lauderdale, FL 33316	Protocol for a Study Comparing Corticaine Cream with Appropriate Controls in the Relief of Symptoms and Inflammation Associated with Acute Hemorrhoids.
Pfizer Pharmaceuticals, New York, NY 10017	Benzyl Alcohol.
Phenex Antiseptic Laboratories, Inc., Chicago, IL 60614	In Vivo and In Vitro Studies of Sodium Salicylic Acid as a Bacterial and Fungal Antiseptic.
The Proprietary Association, Washington, DC 20006	Statement Concerning the Criteria for Placing Category III Ingredients into Category I, Statement on Principles Applicable to Combination Products, Statement on Final Product Testing, Comment on Testing Guidelines.
Schuylkill Chemical Co., Philadelphia, PA 19132	Additional Information on Alcloxa and Allantoin.
Sterling Drug, Inc., New York, NY 10016	Phenylephrine Hydrochloride, Tyloxapol, Tetracaine Hydrochloride.
Trunkey, M.D., San Francisco, CA 94122	Donor Site Wound Protocol.
Whitehall Laboratories, New York, NY 10017	Live Yeast Cell Derivative, The Safety and Effectiveness of SRF as a Wound Healing Agent, Comment on Labeling Claim of "Temporarily Shrinks".

B. Labeled Ingredients Contained in Marketed Products Submitted to the Panel

Acetone sodium bisulfite, alcloxa, amaranth, aromatic oils, atropine, beeswax, benzalkonium chloride, benzocaine, benzyl alcohol, benzyl benzoate, bismuth oxyiodide, bismuth resorcin compound [1], bismuth subcarbonate, bismuth subgallate, bismuth subnitrate, boric acid, boric acid glycerite, cocao butter, calamine, camphor, carbowaxes, cetylpyridinium chloride, chlorobutanol, chlorothymol, cocoa butter, dibucaine, diperodon, dyclonine hydrochloride, *E. coli* vaccines, ephedrine sulfate, epinephrine, eucalyptus oil, extract belladonna, extract of collinsonia (stone root), extract of lappa (burdock root), extract of leptandra (culver's root), gel of alumina, glycerine, goldenseal, hamamelis water (witch hazel water), kaolin, lanolin, lidocaine base, live yeast cell derivative, menthol, methylparaben, mineral oil, mullein, myrrh, oil of cade, oil of mace, oil of turpentine, peruvian balsam, petrolatum, petroleum base, phenacaine hydrochloride, phenol, phenylephrine hydrochloride, phenylmercuric nitrate, paramoxine hydrochloride, prepared calamine, propylene glycol, resorcin, resorcinol, secondary-amyltricresols, shark liver oil, skin respiratory factor, sodium bisulfite, sodium salicylic acid phenolate [2], sulphur, tannic acid, tetracaine, tetracaine hydrochloride, tyloxapol, white wax, white petrolatum, zinc oxide.

[1] This ingredient appears on the label of a product submitted for review: however, it is not an identifiable chemical compound, nor is it officially recognized in the standard compendia. It is a mixture of 50 percent bismuth oxide and 50 percent resorcinol. For the purposes of this report, discussions will be written on bismuth oxide and resorcinol.

[2] This ingredient appears on the label of a product submitted for review: however, it is not an identifiable chemical compound, nor is it officially recognized in the standard compendia. For the purposes of this report, discussion will be focused under sodium salicylic acid phenolate.

Ingredients reviewed by the Panel in addition to the labeled ingredients contained in marketed products submitted to the Panel: Bismuth oxide, coconut oil (palm kernel oil), cod liver oil, dibucaine hydrochloride, epinephrine hydrochloride, epinephrine undecylenate, polyethylene glycol ointment, starch, vitamin A, vitamin D, wool alcohols.

C. Classification of Ingredients

1. *Anorectal active ingredients.* The Panel considered the ingredients with regard to their effect on symptoms related to the perianal, anal, and/or lower rectal areas. As discussed elsewhere in this document, the Panel chose the designation "anorectal ingredients" as more accurately describing the use of these ingredients rather than "hemorrhoidal ingredients." The Panel, therefore, will use the term "anorectal" in referring to these ingredients. (See part II. paragraph A.1. below— Introduction.)

The Panel has classified the following anorectal ingredients submitted to the Panel into groups identified below:

Local Anesthetics

Benzocaine in polyethylene glycol ointment (benzocaine), benzyl alcohol, dibucaine, dibucaine hydrochloride, diperodon, dyclonine hydrochloride, lidocaine (lidocaine base), phenacaine hydrochloride, pramoxine hydrochloride in a cream formulation (pramoxine hydrochloride), pramoxine hydrochloride in a jelly formulation (pramoxine hydrochloride), tetracaine, tetracaine hydrochloride.

Vasoconstrictors

Ephedrine sulfate in aqueous solution (ephedrine sulfate), epinephrine, epinephrine hydrochloride in aqueous solution (epinephrine hydrochloride), epinephrine undecylenate, phenylephrine hydrochloride in aqueous solution (phenylephrine hydrochloride suppositories (phenylephrine hydrochloride).

Protectants

Aluminum hydroxide gel (gel of alumina), bismuth oxide, bismuth subcarbonate, bismuth subgallate, bismuth subnitrate, calamine (prepared calamine), cocoa butter (cacao butter), cod liver oil, glycerin in aqueous solution (glycerine), kaolin, lanolin, mineral oil, shark liver oil, starch, white petrolatum (petrolatum, petroleum base), wool alcohols, zinc oxide.

Counterirritants

Camphor, hydrastis (golden seal), juniper tar (oil of cade), menthol, menthol in aqueous solution, turpentine oil, rectified (oil of turpentine).

Astringents

Calamine (prepared calamine), tannic acid, witch hazel water (hamamelis water), zinc oxide.

Wound-Healing Agents

Cod liver oil, live yeast cell derivative (skin respiratory factor), peruvian balsam, shark liver oil, vitamin A, vitamin D preparations (ergocalciferol and cholecolciferol).

Antiseptics

Boric acid, boroglycerin (boric acid glycerite), hydrastis (golden seal), phenol, resorcinol (resorcin), sodium salicyclic acid phenolate.

Keratolytics

Alcloxa, resorcinol (resorcin), precipitated sulfur (sulphur), sublimed sulfur (sulfur).

Anticholinergics

Atropine, belladonna extract (extract belladonna).

2. Miscellaneous labeled anorectal active ingredients

Collinsonia extract (extract of collinsonia, stone root), *E. coli* vaccines, lappa extract (extract of lappa, burdock root), leptandra extract (extract of leptandra, culver's root), mullein.

3. Ingredients submitted to the Panel and classified as inactive and/or pharmaceutical necessity ingredients

Acetone sodium bisulfite, amaranth, aromatic oils, beeswax, benzolkonium chloride, benzyl benzoate, bismuth oxyiodide, carbowaxes, cetylpyridinium chloride, chlorobutanol, chlorothymol, coconut oil (palm kernel oil), eucalyptus oil, mace oil (oil of mace), methylparaben, myrrh, phenylmercuric nitrate, polyethylene glycol ointment, propylene glycol, secondary amyltricresols (secondary-amyltricresols), sodium bisulfite, tyloxapol, white wax.

D. Referenced OTC Volumes

The "OTC Volumes" cited throughout this document include submissions made by interested persons in response to the call for data notice published in the Federal Register of April 26, 1973, (38 FR 10307). All of the information included in these volumes, except for those deletions which are made in accordance with the confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after June 26, 1980, in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. General Comment

1. *Introduction.* The Advisory Review Panel on OTC Hemorrhoidal Products was charged with the review and evaluation of the safety and effectiveness of single ingredients as well as combinations of such ingredients when used in OTC products for the relief of symptoms associated with hemorrhoids. The Panel interpreted that request as a charge to evaluate products used for the relief of symptoms of disease in the perianal, anal canal, and/or the lower rectal areas. The Panel concludes that when a consumer complains of "piles, hemorrhoids, or rectal problems," the implication is a difficulty in the perianal area, anal canal, and/or the lower rectum.

The Panel finds the term "hemorrhoidal" too restrictive when OTC preparations for "hemorrhoidal disease" are considered. Therefore, instead of the term "hemorrhoidal disease," the terms "anorectal disorders" and/or "anorectal disease" were chosen by the Panel as a more accurate designation, which is defined as those conditions in the lower part of the intestinal tract that interfere with its normal function and/or sensation. The Panel recommends to industry, the medical community, and consumers the use of the term "anorectal" so that in the future a uniform concept is communicated by all.

Anorectal disorders are characterized by the symptoms and signs of bleeding, pain, burning, itching, discomfort, seepage, swelling, protrusion, irritation, inflammation, and changes in bowel pattern or any combination thereof, and may be due to various causes that will be discussed later in this document. (See part II. paragraph E. Below—Therapeutic Claims and Their Rationale.) Not all of these symptoms and signs are amenable to self-diagnosis or self-treatment.

The Panel is aware that there has been no concerted effort to study anorectal disorders and, consequently, our generation has inherited the age-old and difficult problem of treating anorectal diseases empirically. Banov (Ref. 1) has stated that the U.S. Government has spent over 50 billion dollars to study the backside of the moon but not one red cent to study the backsides of its citizens. Unless a concerted effort is undertaken to stimulate research in the anorectal area, the problem will just be passed to the next generation. The Panel on OTC Hemorrhoidal Products is pleased to serve in the review process, knowing that this Panel's work represents the first expenditure of Federal funds related to the study of anorectal disorders.

Anorectal disease, though rare in other animals, is extremely common in humans. No human is immune. The vast majority of adults suffer from one or more anorectal symptoms at some time in their life (Ref. 2). Anorectal disease has caused an unaccountable number of man-hours to be lost annually in industry, commerce, agriculture, and in the military. As with the common cold, millions of Americans have suffered or will suffer from anorectal diseases because of the absence of study programs to increase the knowledge of how to prevent and to treat the diseases of the anorectum (Ref. 2).

Factors thought to contribute to the current high incidence of these disorders are the upright position of man, an increased use of refined foods (lack of roughage), increased sedentary life (lack of physical activity), decreased daily liquid intake, and present day "over concern" with bowel function, leading to the indiscriminate use of laxatives and enemas as indicated in the findings of the Advisory Review Panel on OTC Laxatives, Antidiarrheal, Emetic and Antiemetic Drug Products published in the Federal Register of March 21, 1975 (40 FR 12902).

The first task for the Panel was to accumulate and verify available information, identify misinformation, and establish basic definitions and concepts. Next, a review of the history of anorectal diseases and the assessment of the status of present-day knowledge, of lay and professional people alike, concerning these conditions was developed. In searching for the earliest records, one turns to the medical writings of ancient Egypt where specialists, who treated anorectal diseases, amassed a remarkable amount of practical knowledge. The Egyptians employed suppositories frequently in a variety of anorectal disorders (Ref. 3). They used fatty and oleaginous compounds which this Panel calls emollients.

The Chester Beatty Medical Papyrus, the earliest known treatise, completely devoted to anorectal diseases, presents practical remedies to treat anorectal and other disorders, even though treatment was based entirely on symptoms rather than on specific diseases (Ref. 3).

In 1835, in London, St. Mark's Hospital for Fistula and Other Diseases of the Rectum was founded. This hospital continues to be the mecca where those interested in rectal and colonic diseases come to study. One American, Dr. Charles Boyd Kelsey, was so impressed with St. Mark's Hospital that in 1879, in New York, he started St. Paul's Infirmary (founded on the same general plan as St. Mark's), which has not survived to the present time. Another American, Dr. Joseph Mathews, after studying at St. Mark's, returned to this country and started the American Proctologic Society which later became the present day American Society of Colon and Rectal Surgeons.

In the treatment of anorectal diseases, drugs were employed on an empirical basis. Many of the drugs used throughout history are still in OTC products today. However, modern anorectal therapy emphasizes good anal hygiene as a primary measure and then is followed generally by the application of ingredients which are intended to relieve anorectal symptoms. In many cases, however, treatment may require surgical measures.

Current societal attitudes regarding anorectal diseases encourage secrecy, reticence, shyness, and embarrassment. The average person, as well as some physicians, feels that it is not proper or interesting to talk about anorectal function or diseases. This social and medical shyness regarding the anorectum has contributed to the lack of research relative to diseases of the anorectum.

In early years, child is encouraged to use such euphemisms as "bottom," "fanny," and "behind." Also, the child is taught by the family to use a code name for defecation (bowel movement). The child learns the various terms to avoid saying "toilet" by such evasions as "rest room," "tinkle room," or "potty."

Because ideas relating to the anorectum have not changed significantly over the years by full and open discussion or education, the anorectum has become downgraded and subject to humor. This makes it difficult for consumers with anorectal diseases or conditions to seek out information and/or obtain help for their anorectal problems.

The Panel believes medical schools neglect the teaching of anorectal diseases. This neglect is reflected in the decreased interest of practicing physicians and has produced a relatively high degree of ignorance of anorectal hygiene and diseases which adds to the problem of the affected consumer's desire to obtain relief. There is great confusion and difference of opinion concerning anatomical and physiological terms and definitions. It is not surprising that the consumer does not realize that continued self-treatment of the symptoms associated with "hemorrhoids" may be masking more serious medical problems such as anal fissures, fistulae, abscesses, verrucae acuminatae (anal warts), pruritis ani (anorectal itching), or fecal impactions. The need for direct and early surgical or medical intervention is indicated in treating such diseases as cancer or inflammatory bowel disease. However, it is unusual for serious diseases to respond to treatment with the ingredients in OTC anorectal products within the 7-day limit discussed elsewhere in this document. (See part II. paragraph E. below—Therapeutic Claims and Their Rationale.) This time limit was chosen for protection of the consumer and is intended to alert the consumer to consult a physician for serious problems.

References

(1) Banov, Jr., L., "Backsides." *Archives of Surgery*, 109:844, 1974.

(2) Kramer, B., "Some New Cures Help Hemorrhoid Sufferers Whose Number is Legion. Painful Surgery is Avoided; Among Methods: Freezing; Debunking Some Myths. Napoleon and Paul Fisher." *The Wall Street Journal*, 182:1 and 19, 1973.

(3) Banov, Jr., L., "The Chester Beatty Medical Papyrus: The Earliest Known Treatise Completely Devoted to Anorectal Diseases," *Surgery*, 58:1037–1043, 1965.

2. *Recommendations.* The Panel has made the following recommendations, based on the preceding discussion: a. Promote a study program on the history and management of anorectal diseases to study these diseases on a more scientific basis.

b. Reevaluate, on a scientific basis, drugs that have been discarded but might be of value when examined in light of our increased knowledge, facilities, and techniques.

c. Form a committee with representatives from the American Society of Colon and Rectal Surgeons, and Anatomists Association, the American College of Surgeons, the American Medical Association, and the pharmaceutical industry and profession

to come to grips with the problem of confusion in terminology, and to develop and define terms acceptable to all. This would provide a common working ground from which further studies of anorectal diseases could be instituted.

d. Form research groups to carry out long-range projects on anorectal disease with Federal funding. This implies the development of formalized research methods. For example, there is a need for a camera with fixed focus to be used in anorectal research so that all the pictures would be standardized. With everyone using the same terminology, methods, and the same documentation by photographs, there would be a better chance to advance the knowledge of the management of anorectal diseases. The results could then be given to many groups and would develop a broader basis for discussion, which would lead to a better chance for the meeting of the minds and hopefully lead to improved treatment and possible prevention of anorectal diseases.

e. Establish a greater emphasis on the teaching of diseases of the anorectum and their treatment in medical schools and in resident training programs.

B. Anatomy of the Anorectal Area

The diseases considered in this document are located in the skin of the perianal area, the anal canal, and the lower portion of the rectum. The perianal area is approximately 7 centimeters (cm) in diameter, and surrounds the anus. This area is covered by skin that normally is somewhat more likely to be moist than exposed skin in other areas of the body. The perianal area contains very sensitive pain fibers.

The external opening of the bowel is the anus. Extending upward from the anus is the anal canal which is roughly 2.5 cm in length and also is lined with skin. At the upper margin of the anal canal is the anorectal line which marks the transition of the mucous membrane lining the rectum.

The mucous membrane of the rectum is highly vascular. It contains no indentifiable pain fibers, but there are receptors for the reflex of defecation that are not limited to the rectal mucosa but occur in the muscular wall as well. These sensations allow the differentiation of gas from feces. Such receptors are also present in the anal canal. The nerves, within the muscular wall of the rectum, are known as contraction receptors or pressure receptors; they allow the patient to perceive the pain of distension. Anal continence is maintained by two sphincters. The internal sphincter functions without any conscious control (involuntary), while the external sphincter is a voluntary muscle. The sphincters extend downward beneath the lining of the anal canal. Beneath the mucous membrane in this area is a network of arteries and veins.

There are three main arteries and concomitant viens in this area. They are known as hemorrhoidal arteries and veins and are denoted as internal when they lie above the anorectal line and external when they lie below this line. Blood from these vessels returns either to the general circulation via the inferior and middle hemorrhoidal veins or through the portal system via the superior hemorrhoidal vein.

These vessels that lie just above and below the anorectal line are remarkable in that there is the suggestion of an arteriovenous shunt. Proof of these arteriovenous shunts has been shown by the demonstration of a high oxygen content in these vessels (Ref. 1). To some observers these tissues are similar to the erectile tissues of the corpus cavernosum of the genital tract (Ref. 2).

The following anatomical terms are used within this document and are defined below:

1. *Anal canal.* The anal canal is the channel that connects the end of the gastrointestinal tract (rectum) with the outside of the body. It averages about 2.5 cm in length.

2. *Anal sphincters.* The anal sphincters are those muscles, encircling the anal canal, that provide muscular control and enable an individual to be continent (not spill or leak fecal material). There are two anal sphincters: (1) the external sphincter—a voluntary muscle which functions under the conscious control of the person, and (2) the internal sphincter—an involuntary muscle that functions without the conscious control by the person.

3. *Anal verge (rima).* The anal verge is the lower limit of the anal canal which also represents the junction of the anal canal and the perianal skin.

4. *Anorectal line (dentate line, pectinate line).* The anorectal line marks the division between the upper end of the anal canal and the rectum. It is slightly above the junction of stratified squamous epithelium that lines that anal canal and the columnar epithelium that lines the rectum. It is at the internal side of this line that the anal crypts or glands are found.

5. *Anal crypts.* Anal crypts are pocketlike formations of the mucosa at the anorectal line. Because they face upward, they can retain small amounts of fecal materials which may cause irritation. This irritation is believed by many to be the cause of subsequent infections and the development of some forms of hemorrhoidal disease.

6. *Anus.* The anus is that external opening of the anal canal which connects the rectum with the outside of the body.

7. *External application.* The application of ingredients to the skin of the perianal area and/or the anal canal. This application excludes the use of pile (rectal) pipes, applicators, or suppositories.

8. *Hemorrhoidal blood vessels.* Directly under the mucous membrane is the plexus of hemorrhoidal vessels. There are two types of hemorrhoidal blood vessels: (a) external hemorrhoidal blood vessels—those vessels that are located below the anorectal line, and (b) internal hemorrhoidal blood vessels—those vessels located directly under the mucous membrane of the lowermost part of the rectum, just above the anorectal line.

9. *Hemorrhoidal tissue (anorectal tissue).* The hemorrhoidal tissue is the soft skin, mucosa, fibrous, and fatty tissue that surrounds the hemorrhoidal blood vessels.

10. *Intrarectal (internal) application.* The delivery of anorectal ingredients through the anal canal and into the lower rectum above the anorectal line by some means, such as a rectal pipe or suppository.

11. *Levator ani.* A large group of muscles that form a support for the pelvic organs, including the rectum.

12. *Perianal area.* The perianal area is that portion of the skin and buttocks immediately surrounding the anus.

13. *Rectum.* The rectum is the lower end of the gastrointestinal tract which extends from the anorectal line up to the sigmoid colon. It is approximately 12 to 15 cm in length and is lined with mucous membrane.

References

(1) Thulesius, O. and J. E. Gjores, "Arterio-Venous Anastomoses in the Anal Region with Reference to the Pathogenesis and Treatment of Haemorrhoids." *Acta Chirurgica Scandinavica*, 139:476–478, 1973.

(2) Stelzner, F., "Die Anatomie des Kontinenzorgans," *in* "Die Anorectalen Fisteln," 2d Ed., Springer-Verlag, New York, p. 20, 1976.

C. Anorectal Physiology in a Healthy State

The anus and the anal canal are surrounded by the two circular muscles which together form the anal sphincters. In the normal state, the anal canal and anus are closed, and the individual does not leak fecal material and/or mucus discharge from the rectal mucosa. The muscle can be made to close more tightly under voluntary control.

The anal canal itself is covered with skin and has sensory nerve fibers. This

area shares with the genital organs the characteristic of having increased sensory nerve fibers which, in the presence of disease, can lead to great discomfort. Healthy skin acts as a protective barrier which significantly limits absorption of substances into the body. Therefore, treatment in the area of the anal canal will essentially produce a local effect. In disease, the integrity of the skin barrier is altered and absorption can increase. Loss of protective oils from the cells of the skin itself can lead to damage and/or death of the cells.

The upper end of the anal canal is demarcated by the anorectal line which divides the anal canal from the rectum. The anal crypts are located at this line. They are pockets that in the erect position face upward; they can fill with small amounts of liquid and feces and subsequently are unable to empty themselves. This can lead to irritation and inflammation, which may lead to anorectal disease.

The rectum is lined with a mucous membrane. It does not contain pain sensory nerve fibers. The rectum shares with the rest of the colon only a sense of discomfort when significantly distended. Healthy mucous membrane permits a high degree of absorption of substances, especially water, through the rectal wall. Directly under the mucous membrane is the plexus of hemorrhoidal vessels. There are three divisions of the hemorrhoidal veins by which blood is returned to the heart—the superior, middle, and inferior hemorrhoidal veins. Blood from the superior hemorrhoidal veins drains into the portal system which passes through the liver on the first circulation of blood throughout the body. Blood draining from the inferior and middle hemorrhoidal veins passes into the caval system which by-passes the liver in the first circulation of the blood through the body. Thus, substances which are absorbed through the mucous membrane of the wall of the rectum do not always circulate through the liver to be metabolized. Medication applied into this area may exert a systemic effect due to rectal absorption and immediate transfer into the caval circulation. This can be potentially dangerous with some drugs and will be discussed later in this document. (See part II. paragraph G. below—Bioavailability of Anorectal Dosage Forms and part II. pargraph H. below-Rectal Absorption.)

The anus and anal canal function as an exit through which the body eliminates part of its waste products. It is important to remember that the anorectal area is regularly being covered with feces, which contain digested and undigested food and a multitude of organisms. Healthy skin of the anus and anal canal and healthy rectal mucosa act as a barrier to protect the body from invasion by the bacteria in the feces and from injury due to unabsorbed roughage.

The rectum itself my be empty, except for small amounts of mucous, or may contain feces. When feces are moving down from the colon, they fill and distend the rectum, thereby activating the rectal reflexes which leads to defecation or the passing of the feces out through the anal canal.

The rectal pH varies from nearly netural to highly alkaline (Ref. 1). This pH will influence the absorption or activity of ingredients placed within the rectum. (See part II. paragraph G. 2. c. below—Physiologic factors.)

Reference

(1) Granet, E., "Manual of Proctology," The Yearbook Publishers, Inc., Chicago, IL, pp. 259–260, 1954.

D. The Anorectum in a Diseased State

The anorectal area is subject to a variety of diseases. The most important to the consumer is that of hemorrhoids that are abnormally large or symptomatic conglomerates of blood vessels, supporting tissue, and overlying mucous membrane or skin. When this condition occurs, the consumer will attempt self-treatment first to relieve the symptoms of burning, pain, itching, swelling, and complaints of inflammation or irritation. Other common lesions of the anorectal area include fissures; perianal abscesses; fistulas; warts; and various tumors such as cancer or polyps which can cause persistent symptoms, including bleeding, that are not amenable to self-treatment.

Although many theories are to be found in the literature, the precise causative factor or factors of anorectal disease are not agreed upon. Hence, there are no known means to prevent anorectal disease.

Historically, the chief cause for the development of hemorrhoids has been accepted to be an inadequate venous return and resultant pooling of venous blood. Venous return is made difficult by such considerations as an erect posture and straining during defecation. Because of man's erect position and because there are no valves in the veins of the portal system, there is a network of blood vessels extending from the liver to the anus that will produce continued pressure in the anorectum. A further block of the portal veins by infection or by severe cirrhosis of the liver will increase this pressure and may be followed by the production of hemorrhoids. Pregnancy is associated with increased pelvic pressure and is frequently complicated by hemorrhoids. Heredity may play a role in the tendency to develop anorectal disease.

Another plausible concept to explain the development of anorectal disorders is that, initially, an infection develops in the anal crypts. The infection may exist without the individual even being aware of it. At some unpredictable time the inflammation spreads. It veins are near the inflamed crypt, an inflammation about the veins (periphlebitis) may develop which would involve the vein wall (phlebitis), then the vein lining (endophlebitis), and end up with clot formation (thrombophlebitis), which is known clinically as a thrombosed hemorrhoid. Sometimes the vein wall ruptures and blood infiltrates the tissues outside the vein, producing a hematoma. This is also known as a thrombosed hemorrhoid. Also, the inflammation of the crypt may be the cause of a fissure, abscess, or fistula.

Increased inflammation followed by pain that causes the individual to become aware of the anorectal region. The greater the inflammation, the greater the pain. Sometimes the anorectal inflammation may subside spontaneously. Some OTC anorectoal products claim to contribute to reduction of inflammation. On the other hand, the inflammation may progress and require treatment by a physician.

Stelzner (Ref. 1) has advanced the novel and plausible concept that hemorrhoids resemble the corpus cavarnosum penis. He observed the resemblance of the connective tissue architecture of hemorrhoids with that of corpus cavernosum penis and further noted that the large vascular cavities were filled directly by arteries or arteriovenous anastomoses. The blood in the vessels was present only as a filling material. There were no capillaries present in the corpus. Morevoer, the bleeding in and around the anal canal was predominately arterial. The corpus cavernosum has been demonstrated by arteriography. This concept is consistent with the findings of Thulesius and Gjores (Ref. 2) who showed by gas analysis that the blood in the hemorrhoids was arterial blood. This new concept may provide insight into other possible methods of treatment.

References

(1) Stelzner, F., "Die Anatomie des Kontinenzorgans," *in* "Die Anorectalen Fisteln, 2d Ed., Springer-Verlag, New York, p. 20, 1976.

(2) Thulesius, O. and J. E. Gjores; "Arterio-Venous Anastomoses in the Anal Region with Reference to the Pathogenesis and Treatment of Haemorrhoids," *Acta Chirurgica Scandinavica*, 139:476–478, 1973.

The Panel has developed the following definitions for important diseases affecting the anorectal area:

1. *Hemorrhoids.* Hemorrhoids are abnormally large or symptomatic conglomerates of blood vessels, supporting tissues, and overlying mucous membrane or skin of the anorectal area.

2. *Internal hemorrhoid.* An abnormal conglomerate mass of blood vessels and swollen tissues that arises above the anorectal line.

3. *External hemorrhoid.* An abnormal conglomerate mass of blood vessels and swollen tissues that arises below the anorectal line. The designation "hemorrhoids" is used interchangeably with "piles" and is understood by the consumer to be a swelling. It constitutes a very large part of anorectal conditions for which the consumer seeks relief. Adults between 20 and 50 years of age show the highest rate of incidence and most frequently have more than one anorectal symptom.

4. *Skin tags.* Remnants of hemorrhoids which have recovered from swelling but did not fully return to their original condition.

5. *Thrombosed external hemorrhoid.* A clot that develops in a hemorrhoidal vein in the anal or adjacent to the anus, or a rupture of a hemorrhoidal vessel and an accumulation of blood beneath the skin.

6. *Prolapsed hemorrhoid.* A protrusion of enlarged internal hemorrhoids into the anal canal or extending through the anus.

7. *Rectal prolapse.* A protrusion of a portion of the rectal wall through the anal canal. It may or may not involve the whole circumference of the rectal tissue but usually includes hemorrhoids. It is a serious condition requiring the attention of a physician.

8. *Perianal, perianorectal, or perirectal abscess (collection of pus).* An infection caused by the penetration of bacteria into subcutaneous or submucosal tissues resulting in a localized collection of pus.

9. *Anal fistula (fistula-in-ano).* An inflamed channel or tract connecting the anorectum and the perianal skin which develops due to increased pressure from bacterial infection in the submucosal and subcutaneous anorectal tissues, and which may discharge feces and/or pus intermittently.

10. *Anal fissure (fissure-in-ano).* A painful crack or ulcer in the skin of the anal canal.

11. *Pruritus ani (anal itch).* The medical term denoting persistent itch in the perianal area and/or anal canal.

12. *Anorectal cancer.* A malignant tumor usually manifested by bleeding, change in bowel habit, and/or a constant desire to defecate unrelieved by the passage of a stool.

13. *Polyp.* A benign tumor consisting of mucous membrane and submucosal tissues arising in the rectum.

E. Therapeutic Claims and Their Rationale

The Panel emphasizes that the main objective in the treatment of anorectal disease by OTC preparations is the relief of symptoms associated with anorectal disorders and disease. Consequently, it is necessary to identify the important symptoms that occur with anorectal disease and then to discuss the pharmacologic groups of agents that are intended to relieve these specific symptoms. This is summarized in a chart elsewhere within this document. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.)

Any discomfort of the anorectal area is, at the outset, usually regarded as resulting from irritation of inflammation. Most people tend to consider symptoms of bleeding, pain, itching, burning, seepage, swelling, or protrusion to be caused by or associated with hemorrhoids and buy "hemorrhoidal" preparations to relieve these symptoms. However, these symptoms can be caused by a variety of disease conditions. (See part II. paragraph D. above—The Anorectum in a Diseased State.) Accordingly, the Panel emphasizes that OTC anorectal preparations can relieve certain symptoms but do not necessarily cure diseases. Symptoms should be significantly relieved, if not completely cleared, in reasonable period of time, i.e., in 7 days, and the Panel, therefore, concludes that if symptoms persist for more than 7 days, the consumer should consult a physician.

1. *Itching.* It is produced by a mild stimulus of the sensory nerve fibers which leads to scratching. This symptom is also called pruritus and occurs with many anorectal disorders. When itching persists in the anal and perianal area, despite good hygiene and the use of the usual anorectal products, it is termed pruritus ani. The Panel is aware that the most common symptom of all anorectal disorders is "itching" and that all anorectal active ingredients directly or indirectly deal with this symptom to some degree. The words "itching" and "anal itching" are assumed, in the rest of this document, to refer to the anal and/or the perianal areas.

Itching has affected mankind throughout the ages. Ancient Egyptian medical records list many remedies to treat anal itching; some of them are still employed today.

The causes of anal itching can be classified into several different groups. In general, itching can be secondary to swelling or moisture in this area. It may be due to local sensitivity of the skin to irritants in clothes, in detergents, or in fecal contents. Fungal infections that may be associated with diabetes mellitus or parasites, e.g., anorectal pathologic lesions and pinworms, can also cause itching. In some instances, the precise cause cannot be determined and in others it appears to be due to some psychological cause. However, the individual with intense anal itch is more concerned about relief than the cause.

The Panel has defined antipruritic agent as one that relieves itching and has concluded that local anesthetics, vasoconstrictors, protectants, counterirritants, astringents, wound-healing agents, antiseptic, and keratolytics act as antipruritics. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.) Products containing any Category I ingredient in these groups will be allowed to claim "relief of itching" as designated within the appropriate Category I labeling sections within this document.

An important factor that most often leads to symptomatic relief of itching from anorectal disorders is improved anal hygiene. In connection with good health practices involving the lower part of the torso, vaginal hygiene has been stressed, but little has been said about anal hygiene. Washing the anorectal area with soap with water and carefully removing the soap on a daily basis and after each bowel movement greatly aids in the relief of symptoms and may prevent recurrence of perianal itching. Of importance in anal hygiene is patting or blotting rather than rubbing the skin of the irritated perianal area to avoid further irritation. Patients with anorectal symptoms should be encouraged to sit in warm water as an additional simple means of therapy, two to three times daily, for 15 to 29 minutes; this is called a sitz bath.

The labeling of anorectal products must state that if itching persists for more than 7 days, consult a physician because it is much easier to relieve the symptoms of an acute case of itching than it is to treat a chronic case. (See part II. paragrpah Q. below—Labeling.)

2. *Burning.* Burning is considered, in relationship to itching, to be the next

higher degree or irritation of sensory nerves in the anorectal area. Such sensations vary from a mild itch to be a sensation of pain described as intense heat, such as occurs after picking up hot objects without protection. The relief of burning can be obtained by use of some anorectal ingredients such as local anesthetics, protectants, counterirritants, astringents, wound-healing agents and antiseptics. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.) Any Category I ingredient in these groups will be allowed to claim "relief of burning" as designated within the appropriate Category I labeling sections within this document.

3. *Pain.* Pain can occur as an intensely uncomfortable stimulation of the sensory nerve fibers in the anorectal area. Minor degrees of pain may be caused by either irritation or inflammation. The Advisory Review Panel on OTC Internal Analgesic, Antipyretic, and Antirheumatic Drug Products included some cogent observations as published in the Federal Register of July 8, 1977 (42 FR 35346) on the nature of pain and why pain defies definition despite the fact that everyone has experienced it. That Panel recognizes, as does this Panel, that minor pain can be distinguised by the consumer and provides a reasonable goal for OTC anorectal drug products. Severe pain in the anoretal area signals conditions that should cause the consumer to consult a physician.

The relief of pain can be obtained by use of local anesthetics, vasoconstrictors, counterirritants, astringents, wound-healing agents, and antiseptics. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.) Any Category I ingredient in these groups will be allowed to claim "relief of pain" as designated within the appropriate Category I labeling sections within this document.

4. *Inflammation.* Inflammation refers to a condition in which the affected tissues have reacted to produce pain, heat, redness, and swelling. It usually is due to infection with a microorganism, allergy, or to undue trauma.

The cause is sometimes difficult for a physician to establish so that specific treatment can be initiated. It is unreasonable for the consumer to be expected to establish the cause of inflammation because specialized knowledge is required and there is the additional obstacle of directly viewing the anorectal area. The consumer can reasonably recognize the symptoms of pain, burning, itching, and swelling, which may result from inflammation or irritation and choose anorectal ingredients that are effective in the temporary relief of these symptoms. The relief of inflammation can be obtained by use of protectants, wound-healing agents, and antiseptics. (See part II. paragrpah F. below—Pharmacologic Groups and Relief of Symptoms.) Any Category I ingredient in these groups will be allowed to claim "relief of inflammation" as designated within the appropriate Category I labeling sections within this document.

5. *Irritation.* Irritation in the anorectal area is a condition resulting from stimulation of nerve endings by various causes. This condition is recognized by the consumer to the exent that it causes pain, burning, itching, or swelling. The relief of irritation can be obtained by use of local anesthetics, protectants, counterirritants, astringents, wound-healing agents, and antiseptics. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.) Any Category I ingredient in these groups will be allowed to claim "relief of irritation" as designated within the appropriate Category I labeling sections within this document.

6. *Swelling.* Swelling represents the temporary enlargement of cells and/or tissue due to excess fluid associated with hemorrhoids or hemorrhoidal tissue. The relief of swelling can be obtained by use of vasoconstrictors, wound-healing agent, and antiseptics. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.) Any Category I ingredient in these groups will be allowed to claim "relief of swelling" as designated within the appropriate Category I labeling sections within this document.

7. *Protrusion.* Protrusion is defined as the appearance of hemorrhoidal or rectal tissue outside the anal canal. It can follow swelling of hemorrhoidal tissue and/or loss of muscular support. This symptom is not treatable by OTC preparations and a physician should be consulted.

8. *Seepage.* Seepage is the leaking of either fecal material and/or mucus from a partly open (incontinent) anal sphincter. It may include the discharge of pus from a fistula or feces through a fistula that connects the rectum to the anal canal. In either case, a physician should be consulted because OTC products are not available for relief of this condition.

9. *Bleeding.* Bleeding is a common symptom of anorectal disease and may indicate malignant disease of the colon and/or rectum. This symptom should never be regarded lightly. The Panel concludes that this symptom must not be treated by OTC preparations. A physician should be consulted so that a complete examination of the individual may be made.

10. *Discomfort.* Discomfort is defined in part by Webster's Third International Dictionary as a "mental or physical uneasiness, less intense and less localized than pain." Discomfort in the anorectal area may refer to any or all of the following symptoms: burning, irritation, itching, pain, or swelling. The relief of discomfort can be obtained by use of local anesthetics, vasoconstrictors, protectants, counterirritants, astringents, wound-healing agents, and antiseptics. (See part II. paragraph F. below—Pharmacologic Groups and Relief of Symptoms.) Any Category I ingredient in these groups will be allowed to claim "relief of discomfort" as designated within the appropriate Category I labeling sections within this document.

F. Pharmacologic Groups and Relief of Symptoms

The Panel wishes to emphasize certain elementary principles. It recommends as a primary approach to relief of symptoms that all OTC anorectal products carry the instructions "When practical, wash the anorectal area with mild soap and warm water and rinse off all soap before application of this product." (See part II. paragraph Q. below-Labeling.) Furthermore, OTC products that are used to relieve the symptoms discussed within this document should be applied or inserted after bowel movements rather than before because in the latter case the effect would be lost.

OTC anorectal ingedients can be classified into several groups on the basis of their pharmacologic action. The anorectal ingredients discussed within this document were classified on the basis of their pharmacologic activity—local anesthetics, vasoconstrictors, protectants, counterirritants, astringents, wound-healing agents, antiseptics, keratolytics, and anticholinergics. As an aid in evaluating the effectiveness of individual OTC anorectal ingredients to relieve the symptoms associated with anorectal disorders, the Panel constructed the following chart in which each pharmacologic group was classified with respect to its effectiveness, generally, in relieving each of the symptoms associated with anorectal disorders, i.e., itching, discomfort, irritation, burning, swelling, pain, inflammation, protrusion, seepage, and bleeding:

Common Symptoms for Which Anorectal Ingredients Are Used and Their Effectiveness

	Local anesthetics	Vasoconstrictors	Protectants	Counterirritants	Astringents	Wound-healing agents,[1]	Antiseptics	Keratolytics	Anticholinergics[2]
Itching	+	+	+	+	+	±	±	+	(–)
Discomfort	+	±	+	+	+	±	±	(–)	(–)
Irritation	+	(–)	+	±	+	±	±	(–)	(–)
Burning	+	(–)	+	±	±	±	±	(–)	(–)
Swelling	(–)	+	(–)	(–)	–	±	±	(–)	(–)
Pain	+	±	(–)	+	+	±	±	(–)	(–)
Inflamation	(–)	(–)	±	(–)	(–)	±	±	(–)	(–)

Protrusion: Labeling not appropriate for OTC products. (See part II. paragraph E.7 above—Protrusion.)
Seepage: Labeling not appropriate for OTC products. (See part II. paragraph E.8 above—Seepage.)
Bleeding: Labeling not appropriate for OTC products. (See part II. paragraph E.9 above—Bleeding.)

[1] All ingredients are Category III.
[2] All ingredients are Category II.
(+) Indicates that symptoms will be relieved (Category I).
(–) Expected not to relieve (Category II).
(±) May relieve (Category III).

The following definitions were developed by the Panel as they apply to the specific pharmacologic groups discussed within this document:

1. *Absorbent.* An agent that takes up within itself fluids or other substances on, or secreted by, the skin or muccous membranes.

2. *Adsorbent.* An agent that because of its fine state of subdivision, is capable of attaching other substances onto its extensive surface area.

3. *Anticholinergic.* An agent that inhibits or prevents the action of acetylcholine, the transmitter of cholinergic nerve impulses.

4. *Antiseptic.* An agent that will inhibit the growth and development of microorganisms but will not necessarily destroy them.

5. *Antipruritic.* An agent that reduces or abolishes the sensation of itching.

6. *Astringent.* An agent that is applied to the skin or mucous membranes for a local, limited, usually reversible, protein-coagulant effect.

7. *Bacteriostat.* An agent that arrests or hinders the growth of bacteria.

8. *Counterirritant.* An agent that produces a local sensation that distracts from the perception of pain, burning, or itching. The perception of these symptoms are distracted and commonly replaced by warmth, cooling, or tingling sensations.

9. *Demulcent.* An agent that forms colloidal solutions and because of its cohesiveness has the capacity to protect skin surfaces in a manner similar to that of mucus.

10. *Emollient.* An agent used to soften or protect internal or external body surfaces.

11. *Emulsifier.* An agent that promotes the uniform distribution of one substance into another.

12. *Germicide.* An agent that kills pathogenic microorganisms and that is intended for use on inanimate objects and surfaces.

13. *Kedratolytic.* An agent that produces desquamation (loosening) and debridement (sloughing) of surface tissue cells of the epidermis.

14. *Local Anesthetic.* An agent that produces temporary local disappearance of pain, burning, itching, discomfort, and/or irritation by reversibly blocking nerve condition when applied to nerve tissue in appropriate concentrations. The term "topical anesthetic" is included by the Panel in this definition.

15. *Lubricant.* An agent that reduces surface tension and friction between two surfaces.

16. *Protectants (includes absorbents, adsorbents, demulcents, and emollients).* Agents that, when applied to the skin or mucous membranes, provide a physical barrier that forms a protective coating over tissues.

17. *Vasoconstrictor.* An agent that causes temporary constriction of the blood vessels.

18. *Vehicle.* A usually inert agent or combination of agents used to confer desirable consistency or form or to serve as a suitable carrier for the active ingredients.

19. *Wound-healing agent.* An agent that increases the rate of healing of a wound compared with the rate of healing of a wound that is untreated or treated only with protectants.

G. *Bioavailability of Anorectal Dosage Forms*

1. *General comment.* The Panel requires final formulation testing based on the following discussion. The Panel concurs with the definition of bioavailability as published in the Federal Register of January 7, 1977 (43 FR 1624), which is the rate and extent to which the active drug ingredient or therapeutic moiety is absorbed from the drug product and becomes available to the site of drug action. Bioavailability is usually determined by measurement of the concentration of the active drug ingredient or therapeutic moiety, or its metabolites in biologic fluids, or in urine as a function of time, or by an appropriate acute pharmacologic effect.

For most drugs, bioavailability is determined by measuring the active drug in the systemic circulation. Bioavailability of a drug is not related to what occurs after the drug enters the systemic circulation, such as distribution, binding, metabolism, or excretion. These processes influence the concentration of a drug throughout the organism, but they have no bearing on its bioavailability.

The bioavailability of the active ingredient in an OTC anorectal drug product is a function of the physiocochemical properties of the active ingredients but is by no means determined solely by them. The clinical application of the bioavailability concept is not primarily limited to the pharmacologically active ingredients but more so to certain characteristics of the drug products available for therapeutic use under the circumstances of such use. This concept applies to the fact that active ingredients may not be available because of the presence of certain inactive ingredients, and there may be individual variations in anatomy and physiology that will modify bioavailability. Thus, the bioavailability of OTC anorectal drugs is dependent upon the interaction of such characteristics as the physiocochemical properties, the formulation, the manufacturing process of the drug, and physiological factors, as well as upon drug dosage, dosage form, and the site of application (externally or intrarectally). In the case of anorectal absorption, the bioavailability of a drug is determined by its release from its vehicle, its solubility in the rectal fluids, diffusion to the absorbing membrane, and transfer into the body via the vascular bed perfusing the tissue (Ref. 1).

2. *Factors influencing bioavailability—a. Physicochemical properties of drugs.* The lipid-water solubility of a drug (lipid-water partition coefficient) must be considered in choosing a base for drugs administered anorectally. A drug which is highly soluble in a fatty base and present in low concentration is slowly released from its base and has only a slight tendency to diffuse into the small amount of aqueous rectal fluid. A drug which is slightly soluble in the fatty base and present in a concentration

close to its saturation will diffuse more readily into the aqueous rectal fluid (Refs. 2 through 5). Thus, water-soluble, oil-insoluble salts, e.g., ephedrine sulfate, are preferred for rapid absorption from a fat-type base, e.g., cocoa butter. For a water-soluble or water-miscible type base, e.g., polyethylene glycol, a water-soluble salt is preferred for more rapid drug absorption. The rate-limiting step in absorption for drugs incorporated in a fatty base seems to be the transfer of the drug from the base to the rectal fluid. In the case of water-soluble or water miscible-bases, the rate-limiting step in absorption seems to be drug transfer through the rectal mucosa (Ref. 3).

The rate of drug release from its base may be increased by increasing the concentration of the active ingredients. However, it appears that after a certain limit is reached any further increase in concentration has little effect on absorption. Absorption of drugs through the anorectal barrier is considered to be a matter of simple diffusion across a permeable membrane. In contrast, diffusion of a drug from its base is a function of the drug's concentration as well as such properties as its solubility in the anorectal fluids, the ionization or dissociation constant of the drug, the dissolution rate of the drug from the dosage form, the pH of the base, the particle size of the drug, and the presence of other ingredients that may interact with the active drug (Refs. 2 and 6).

All of the above factors may greatly affect the actual safety and effectiveness of an anorectal product, and this is the basis on which the Panel requires final formulation testing.

b. *Formulation and manufacture of the drug product.* OTC anorectal drug products are compounded and manufactured by a variety of techniques. Thus, the formulation and manufacturing process can greatly influence the bioavailability of the active ingredient in an anorectal drug product.

In the formulation of suppositories, for example, viscosity-increasing agents or other additives may be necessary to stabilize the physical properties of the suppository, i.e., prevent softening of the base which makes administration difficult or prevent rapid settling of suspended drug particles in melted base, during the molding process (Refs. 3 and 4). The inclusion of surface-active agents is usually necessary in the formulation of anorectal dosage forms, e.g., ointments, creams, and suppositories. Their presence may increase or decrease absorption rate. The surfactant may reduce the surface tension of the mucous blanket that covers the rectal membrane, creating an environment favoring drug absorption. It may also act as a solubilizing agent for the active ingredient, and the solubilized form may be absorbed more readily. By contrast, the surfactant may decrease absorption rate through the formation of a drug-surfactant complex (Refs. 7, 8, and 9). The data available on the relationship of surfactants to drug release and absorption is limited, making predictions difficult.

Drug release and absorption may also be influenced by the manufacturing process. For example, the temperature used for melting cocoa butter, which exhibits marked polymorphism (the property of existing in different crystalline forms), must be carefully controlled. Each polymorphous form of cocoa butter has different melting points as well as different release rates. The formation of the various polymorphous forms of cocoa butter depends upon the degree of heating, on the cooling process, and on various other factors during this process (Refs. 3, 4, and 5).

These variable factors likewise affect overall safety and effectiveness of an individual ingredient and thus further justify the need for final formulation testing.

c. *Physiological factors.* Anorectal physiology may also be a factor affecting anorectal drug absorption. In the absence of fecal matter, the rectum contains a small amount of aqueous fluid with a pH of approximately 7.2, but of very low buffering capacity. Thus, the pH of this rectal fluid may be affected by the drug(s) dissolved in it. The rectal epithelium is lipoidal in nature; hence, it is preferentially permeable to nonionized drugs. The degree to which penetration occurs is a function of the pH and the ionization constant of the drug. Ordinarily, a mucous blanket covers the rectal mucosa of the rectum, and it may impede the diffusion of drugs into the surrounding tissues (Refs. 3 through 6).

The nature of the blood supply to the anorectal region, involving the hepatic and systemic circulation, may also affect overall drug bioavailability. A drug administered rectally may by-pass the liver to enter the systemic circulation, or it may enter the hepatic system where it may undergo modification in activity. The amount of drug absorbed directly into the general circulation depends upon where the drug is released in the rectum. For example, if a suppository remains in the lower part of the rectum, more of the drug will enter the general circulation, circumventing an initial pass through the liver, than will enter if the suppository moves to the upper regions of the rectum where the upper hemorrhoidal veins, which lead to the liver, predominate. Thus, drug bioavailability may be sharply reduced with drugs that undergo significant hepatic degradation (Refs. 3, 4, and 5).

Additional physiological factors that may influence anorectal drug absorption include fecal impaction, colonic obstruction, body dehydration, and diarrhea. Even muscle tone, which influences movement of anorectal fluids and aids in the disperson of dissolved drugs, may be a factor.

In summary, it appears that the rate-limiting factor in rectal absorption is the diffusion or release of the drug from the base (vehicle). Dissolution of the drug is apparently limited by the small amount of rectal fluid available for interaction with the rectal dosage form. The base may be absorbed at varying rates and carry the drug along with it, or the base may coat the mucous membrane to delay or minimize absorption (Ref. 10). Additionally, the physiochemical characteristics of the drug and vehicle and anorectal physiology must also be considered in evaluating the bioavailability of drugs from OTC anorectal drug products (Ref. 11). The Panel recognizes that the effectiveness of topical application of anorectal drug products is affected by the bioavailability of the active ingredient. However, in addition to absorption through the skin, some products are delivered intrarectally. Bioavailability of the active ingredient of such products becomes a concern for reasons of safety due to absorption through the rectal or colonic mucosa with varying degrees of subsequent systemic effects. Therefore, the Panel concludes the final formulation must be tested for safety and effectiveness because testing of individual ingredients cannot predict either safety or effectiveness of an anorectal drug product.

The Panel emphasizes that bioavailability was an important concern in the review and evaluation of each ingredient categorized in this document. The Panel recognizes that there is, at present, a lack of bioavailability data for many of the drugs discussed in this document. However, when available, the existing data were considered in the evaluation of these ingredients. The Panel also recognizes that as more bioavailability data become available some of the recommendations made in this document may need to be altered to conform to the scientific literature and that the appropriate division within FDA

should review the data and institute appropriate changes.

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H. Rectal Absorption

The phenomenon of rectal absorption of drugs has been studied and discussed (Refs. 1 through 4). Despite the complicated nature of the topic, several statements may be made. Generally, in vitro models, though useful, have little relationship to in vivo drug release until correlated to effectiveness (Refs. 1 and 4). Use of in vivo models (rats and dogs) raises the question of relevancy to human rectal absorption.

The degree and rapidity of absorption has been shown to be a function of many factors such as properties of the vehicle (Ref. 4) and concentration of the active ingredents (see part III. below—Local Anesthetics), formulation (Ref. 4), drug properties (Refs. 1 and 4), drug vehicle interaction (Ref. 5), contents of the rectum (Ref. 2), and the mode of transport through the rectal mucosa (Refs. 4 and 6). It also is probably dependent on relative venous pressure in systemic and portal systems, state of rectal mucosa regarding inflammation, pH and body positioning (upright versus supine).

Medication administered intrarectally can be absorbed into the systemic and/or portal circulation within minutes or much more slowly depending on the above mentioned factors (Ref. 1). The absorption may be greater (Refs. 2 and 7), equal to (Ref. 2), or less than (Refs. 2 and 4) oral administration, and is less consistently predictable than by other routes (Ref. 2). Because of the anatomical relationship in this area, drugs absorbed through the rectal mucosa will be absorbed initially into the caval (systemic) or hepatic (portal) circulation or both, whereas oral drugs pass initially into the portal circulation (Refs. 1 and 4).

Therefore, the Panel concludes that the final formulation must be tested for safety and effectiveness because testing of individual ingredients cannot predict either safety or effectiveness of an anorectal drug product.

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I. Anorectal Dosage Forms

1. *General comment.* Anorectal products may be applied in several ways and are manufactured in corresponding forms. For external application, ointments, creams, pastes, gels, liquids, pads, and foam have been used. For intrarectal use, suppositories, introduction of ointment, creams, and gels by pile pipes or by one's finger, and foam via applicators are the common methods. Ointments, gels, suppositories, and foams will be described in more detail below and are also discussed elsewhere in this document. (See part II. paragraph G. above—Bioavailability of anorectal Dosage Forms and part II. paragraph H. above—rectal Absorption.)

A question was raised concerning the use of dusting powders as a dosage form because some of the ingredients, i.e., zinc oxide, have at various times and for various purposes been used in this manner. However, no submissions were received by the Panel to consider this dosage form. It is not discussed any further in this document.

2. *Ointments, creams, gels, jellies, and pastes.* Ointments are semisolid prepartions for external or intrarectal application and are of such consistency that they may be readily applied to the skin by inunction or inserted into the rectum by means of rectal applicators. They should be of such composition that they soften but do not necessarily melt when applied to the body. They serve as vehicles for the topical application of medicinal substances and also function as protectants and emollients for the skin by forming a continuous layer on the surface. Depending on the site of application, the physiochemical properties of the base, and the ingredients incorporated therein, an ointment may simultaneously act as a protectant, emollient, and vehicle (Ref. 1).

For many years, ointments were limited by definition to mixtures of fatty substances. Today, in addition to such oleaginous mixtures, there are preparations of greater efficiency possessing the same general consistency but with an entirely different appearance, such as water-in-oil and oil-in-water emulsions that are also called creams or pastes (Ref. 1). Jellies and gels are usually water-washable or water-soluble. However, because the definition of creams, pastes, gels, jellies, and ointments overlap on certain characteristics, this designation is less meaningful than the ability of a product to be water-washable or water-resistant as discussed elsewhere in this

document. (See part V. below—Protectants.)

Creams and ointments containing large amounts of insoluble powders are referred to as pastes. Pastes are usually stiffer and more absorptive than creams and ointments (Ref. 1).

Ideally, an ointment base should be nonirritating, nondehydrating, nongreasy, compatible with common ingredients, stable, easily removable with water, absorptive (able to absorb water, and/or other liquids), and able to release incorporated ingredients efficiently. No ointment base possesses all of these characteristics (Ref. 1).

Ointments, including creams and pastes, vary in effect and can have a psychological as well as a soothing effect and protectant action on those patients with anorectal disorders. Ointments can be applied externally or intrarectally unless the active ingredients contained in the product limit usage in some way. Because there are no clear differences between ointments, creams, gels, jellies, and pastes, any of these terms are implied whenever the term "ointment" is used in the following discussions.

a. *External application.* Ointments are applied to the perianal area and the anal canal as a thin covering. Amounts can vary but should cover the entire irritated area. Application of large amounts may be wasteful and could cause excessive hydration and softening of the skin (maceration of the tissues).

b. *Intrarectal application.* In addition to suppositories, pile pipes and other mechanical devices have been developed for intrarectal delivery of anorectal preparations. The main advantage of intrarectal application is patient acceptance. The main disadvantage is the possibility of injury. Some patients prefer applying medication by using their fingers. With a properly functioning anal sphincter (which does not allow seepage of rectal contents) the ointment applied by pile pipe has only a brief contact with the skin of the anus and anal canal. Most of the contact is on the rectal mucosa where the highest degree of absorption occurs. Intrarectal administration of anorectal preparations can be accomplished by suppositories or by tubes that pass through the anal sphincter. These pile pipes are of differing designs but their function is to allow the introduction of a preparation above the anal sphincter so that it may remain in contact with the rectal mucosa where attempted insertion of an ointment by the finger is not apt to be successful.

In the presence of a properly functioning anal sphincter it should be expected that, in the rectum, dispersal of the contents of the container of drug will be dependent upon the force exerted by the delivery system (usually a tube and pile pipe) and the location of the holes in the tip of the pile pipe. The pipe must be long enough to pass through the anal sphincter. Lateral openings near the end of the pipe should allow direct contact with internal hemorrhoids and the lowest portion of the rectal mucosa. A hole only in the end combined with strong pressure could result in wide dispersal as high as the upper portion of the rectum leaving relatively little in the hemorrhoidal area, especially if the consumer lies down immediately after application. If the consumer remains in an upright position, the drug product may be expected to remain in contact with the lower rectum due to the force of gravity.

Pile Pipes can be stiff or flexible. Because there is some danger that the mucosa can be perforated if they are not inserted correctly, tips should be well lubricated and preferably flexible to avoid injury. All applicators should be cleaned before and after use. The label of products to be administered by pile pipes should be accompanied by the following warning, "Do not use this product if the introduction into the rectum causes additional pain. Consult a physician promptly." (See part II. paragraph Q.5. below—Warnings.)

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3. *Suppositories.* Suppositories were known to the Assyrians about 2600 B.C. and were later used by the Egyptians, Greeks, and Romans (Ref. 1). Early Egyptian medical records show a variety of anal conditions and multiple remedies for the treatment of local conditions. Suppositories used in Europe today are employed primarily as a delivery mechanism for drugs that act systemically, whereas the use of suppositories in America is both for a local effect and less frequently for systemic effects.

Throughout the centuries, suppositories have been inserted into the rectum for the principal purpose of promoting defecation. During the Middle Ages, fat tallow, candle wax, and soap were employed as suppositories. By 1766, cocoa oil was used in the manufacture of suppositories. In 1888, Dr. Ismar Boas recommended that glycerol suppositories be used for constipation. The rationale was to encourage easier, more comfortable bowel movements. An easier bowel movement is what the person with an anorectal disorder has always welcomed.

For those consumers with anorectal disorders, the suppository has a great psychological effect. It makes the person feel as if something is really being done to cure the disorder when in fact only a temporary relief of symptoms has been achieved. A suppository, with its lubricating properties, in some cases, may ease the passage of feces and may decrease other anorectal symptoms. However, the use of the suppository may delay the person from seeking needed medical or surgical care unless limitations of use are carefully read and followed by the consumer.

With a properly functioning anal sphincter, i.e., one that does not allow seepage of rectal contents, the inserted suppository has only a brief contact with the skin of the anal canal. Most of the contact is on the rectal mucosa where the highest degree of absorption occurs. The commonly manufactured "bullet shaped" suppository, after insertion, leaves the site of pain and moves into the rectum and sigmoid. Only when the suppository melts do the active ingredients become available. Instructions to maintain the upright position may give gravity a better chance for the suppository's active ingredients to alleviate symptoms.

The suggestion has been advanced that the suppository should be shaped preferably like an "hour glass" or "collar button" so that it remains in the anal canal. This concept merits further study.

The Panel is aware of many cases of rectal or colonic cancer (Refs. 2, 3, and 4). The Panel is concerned that reliance upon prolonged suppository use to self-treat symptoms may cause delay in seeking definitive medical care.

Increased education in regard to proper usage of suppositories in anorectal disorders should be promoted.

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4. *Foams.* A specially designed applicator which is claimed to deposit

medication externally (in the anal canal) and in the lower rectum was submitted to the Panel (Ref. 1). The applicator is designed for use with a foam that incorporates the active ingredient. The design of the applicator is intended to overcome the inadequacies of suppositories. As indicated in the above discussion on suppositories, the medication applied to the anal canal is minute as the suppository passes into the rectum. The suppository will travel to the upper rectum if the consumer is prone; is the consumer is erect it will remain the the lower rectum. The ability of foam to remain in the anal canal and the lower rectum will be affected by formulation, which in turn will control the duration of effectiveness of the active ingredient. Therefore, in the opinion of the Panel, it is necessary for each foam product to be tested for effectiveness in final formulation against foam without active ingredient.

It is not reasonable to extrapolate the results of one foam product to another because the mixture of propellant and formulation will effect the size of the bubbles (Refs. 2 and 3). Thus, large bubbles will cause the foam to have a lower concentration of ingredient and smaller bubbles will cause a higher concentration per unit volume. It is important with foams to relate the concentration to a unit volume (ideally, 2 milliliters (mL) which is the volume of approximately 2 grams (g) of water) instead of relating the concentration to a unit of weight as is done with other dosage forms, i.e., suppositories or ointments (ideally, 2 g). The most extreme example of this point would be a single bubble formed by a shell of emulsion that weighs 2 g, with a specific gravity of 1 (for convenience in calculations), which had a useful thickness of 0.65 millimeter (mm). (See part II. paragraph K.3. below—Concept of a 2 g dosage unit and part V. paragraph A. below—General Discussion.) The bubble would have a diameter of approximately 30 mm and a volume of more than 14 mL (slightly larger than a ping pong ball). This calculation makes it clear that foams must relate concentration to volume of the final product because the maximum concentration is achieved when all the bubbles are gone. To substantiate superiority of foam over ointment or any other dosage form, studies that are not currently available must be done.

The proposed ban for the nonessential use of chlorofluorocarbons in products subject to FDA control as published in the Federal Register of March 17, 1978 (43 FR 11301) did not exempt anorectal products; therefore, the propellant in such foam-producing products shall have to be other than halogenated hydrocarbons. The sponsor of one product proposed to replace the halogenated hydrocarbon propellant with isobutane. Other propellants may also be available at a later date, but these ingredients are considered pharmaceutical aids and as such are to be considered later in depth by FDA.

The need to produce a foam for delivering the active ingredient is not clear to the Panel. A properly designed ointment applicator should serve the same purpose, but the Panel does not intend to restrict ingenuity in product design provided the product accomplishes the claimed effect. It has been noted that foam cannot contain as much active ingredient per unit volume as can an ointment because of the mixture with the propellant. This may severely restrict the ability of such a dosage form to meet minimum concentration requirements, e.g., if a foam product claims to be a protectant, which must be present as 50 percent of the dose, and only 30 percent can be incorporated in the metered dose. Such a product cannot make protectant claims and would necessitate reformulation and/or relabeling.

Therefore, foam products must meet the same requirements of safety and effectiveness as any other dosage form, and if any advantage is claimed, studies and data must be provided because related studies and data currently available are not sufficient to establish effectiveness (Ref. 2).

The quantity of drug product most likely to produce results and constitute a reasonably useful amount is discussed elsewhere in this document. (See part II. paragraph K.3. below—Concept of a 2-g dosage unit.)

References

(1) OTC Volume 120039.

(2) Augsburger, L. L., "Aerosol Shave Cream Evaluation," *Soap and Chemical Specialties,* 44:43–46 and 107–110, 1968.

(3) Augsburger, L. L. and R. F. Shangraw, "Bubble Size Analysis of High Consistency Aerosol Foams and Its Relationship to Foam Rheology. Effects of Container Emptying, Propellent Type, and Time," *Journal of Pharmaceutical Sciences,* 57:624–631, 1968.

J. Allergy and Sensitization of the Anorectal Area

Adverse reactions to topical ingredients usually consist of one or more of the following: Photosensitization, sensitization to irritants, allergic reactions, and systemic toxicity (Refs. 1 through 7). Because of present societal attitudes, photosensitization of the anal area is not of importance, and systemic toxicity will be discussed in reference to specific pharmacologic groups, when appropriate, elsewhere in this document.

Allergic, sensitization, or irritative reactions were considered in the process of evaluating the safety and effectiveness of OTC anorectal products. The perianal skin is usually occluded by clothing, and often moisture and increased warmth persist which, in the presence of the many ingredients found in OTC and prescription anorectal products, cause a greater number of adverse reactions than the same products when applied to skin that is dry and not occluded.

Exact incidence of primary irritant or allergenic reactions has not been established and is influenced by various factors (Ref. 3). Many investigators as well as the International Contact Dermatitis Research Group (ICDRG), an outgrowth of the North American and European Contact Dermatitis Research Group (NACDRG and ECDRG), have been executing studies in patch testing and, simultaneously, are attempting to standardize methods of testing and reporting (Refs. 1 and 3 through 6). Stolley (Ref. 2) has stated that approximately 5 percent of all hospital admissions are for varying degrees of adverse reaction to drugs and approximately 15 percent of the patients seeking medical services are admitted for the treatment of adverse reactions (Ref. 2). It is more difficult to establish definite figures for outpatients. Often the symptoms of an adverse reaction to a medication applied to the diseased anorectal area are similar to the symptoms of the disease, so a patient only presumes the medicine is not helping. Studies performed in dermatology clinics are beginning to give more definite estimates of incidence of outpatient reactions (Refs. 1, 3, 4, and 5).

Many OTC anorectal products contain ingredients that may have an allergic or sensitizing potential. In North American and European studies, reactions to balsam of Peru, an ingredient used in some OTC anorectal products, ranged from an incidence of 0.4 to 28 percent (Ref. 6). Cross reaction to other perfumes was also noted because many different types of perfumes are used on OTC anorectal products (Ref. 3). In North America, the widespread availability of topical medications containing local anesthetics is believed to account for the reaction rate of 8.4 percent. Criteria and studies for evaluating allergenic or sensitizing compounds are well-defined (Refs. 1, 3, and 7). Some additional aspects of sensitization and allergy are discussed

elsewhere in this document. (See part V. paragraph B.1.g. below—Lanolin (external and intrarectal use).)

The Panel concludes that, although a certain portion of the population will experience allergic or sensitization reactions from the use of OTC anorectal preparations, in general, these preparations can be used safely without allergic reaction by most individuals at the recommended dosages. In those instances where allergenicity or sensitization from specific ingredients are important considerations for labeling, the Panel has specified an appropriate warning to be included in that ingredient's labeling.

References

(1) Marzulli, F. N. and H. I. Maibach, "The Use of Graded Concentrations in Studying Skin Sensitizers: Experimental Contact Sensitization in Man," *Food and Cosmetic Toxicology*, 12:219–227, 1974.

(2) Stolley, P. D., "Assuring the Safety and Efficacy of Therapies," *International Journal Health Services*, 4:131–145, 1974.

(3) Fregert, S. et al., "Epidemiology of Contact Dermatitis," *The Transactions St. John's Hospital Dermatological Society*, 55:17–35, 1969.

(4) Summary Minutes of the OTC Panel on Hemorrhoidal Drug Products, 23d Meeting, November 21, 22, and 23, 1976.

(5) Anon., "Epidemiology of Contact Dermatitis in North America: 1972," *Archives of Dermatology*, 108:537–540, 1973.

(6) Marzulli, F. N. and H. I. Maibach, "Contact Allergy: Predictive Testing in Man," *Contact Dermatitis*, 2:1–17, 1976.

(7) Epstein, E., W. J. Rees and H. I. Maibach, "Recent Experience With Routine Patch Test Screening," *Archives of Dermatology*, 98:18–22, 1968.

K. Principles Applicable to Combination Products

1. *General combination policy.* Most anorectal products currently on the market contain ingredients reviewed by the Panel and are promoted or sold to relieve a number of different symptoms. For example, OTC products commonly used for the treatment of the symptoms associated with "hemorrhoids" include ingredients intended to provide relief of one or more concurrent symptoms such as burning, itching, swelling, and pain. These products may contain more than one active ingredient to relieve a spectrum of symptoms.

To clarify the place of combinations in the marketplace, the Panel applied the OTC drug review regulation requirement contained in 21 CFR 330.10(a)(4)(iv) which states that:

> An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The Panel concurs with the regulation and concludes that each active ingredient in a combination product must contribute to the claimed effects and that each active ingredient must be a necessary component for rational therapy of concurrent symptoms.

The Panel has established specific criteria for the treatment of symptoms with combination products. Each Category I combination is currently limited to one active ingredient from any one pharmacologic group, except for protectants as specified elsewhere in this document. (See part II. paragraph K.6. below—The combination of active ingredients from the same pharmacologic group.)

The Panel has placed combinations of two active ingredients from the same pharmacologic group in Category III, except for protectants. Each active ingredient must be generally recognized as safe and effective when used alone for the claimed effects and must make a contribution to the claimed effects when in combination. Therefore, the Panel has recommended only specific combinations be provided and limited to one active ingredient from any one pharmacologic group except for protectants. The Panel recognizes that in the case of the pharmacologic group of wound-healing agents, it may be rational to include more than one such ingredient in a product because of their different mechanisms of action. However, until proven that each wound-healing ingredient makes a significant contribution to the wound-healing effect of the product, the Panel's statement placing such combination products in Category III applies.

The Panel concludes that combinations of ingredients are safe and effective if they provide rational concurrent therapy for a significant existing target population that can benefit from their use. The Panel emphasizes that these combinations must contain adequate directions for use and include warnings against unsafe use. These combinations of active ingredients must clearly specify in their labeling the anorectal symptoms for which they are indicated.

2. *Requirement that ingredients from different pharmacologic groups contribute to the claimed effects.* The Panel has placed certain ingredients in Category I as safe and effective, based on a review of the literature, data submitted, and clinical expertise. However, if a Category III ingredient is to be raised to Category I, it must be shown that it makes a statistically significant therapeutic contribution to the claimed effects.

The Panel considers the following criteria as providing a rational basis for determining the contribution of each active ingredient in an anorectal preparation: (a) Each active ingredient in a combination has been found to be safe and effective (Category I) and its inclusion clearly contributes to the claimed effects as shown by clinical data, and (b) the dosage of each active ingredient must be within the specified dosage range for its claimed therapeutic effects specified in the ingredient statements elsewhere in this document.

3. *Concept of a 2-g dosage unit.* The identification of an average dosage unit was necessary to establish a basic and acceptable minimum quantity for use that provides a therapeutic effect. In considering anorectal products, the Panel concludes that a 2-g dosage unit is reasonable, but this does not imply that other dosage sizes are not acceptable because size could be related to other factors. An official pharmaceutic compendium states that the average suppository weighs 2 g (Ref. 1). It has been previously shown in studies of anorectal products that patients use an average of 2 g per application of ointment (Ref. 2). The Panel recognizes that exceptions as to dosage unit size do occur, but that the 2-g dosage unit permits the relationship of a safe use concentration to a suitable dosage unit size.

Further justification for the use of an average dosage unit of 2 g is provided by the calculation that such a quantity of ointment with a specific gravity of 1.0 would cover an area 10 cm^2 at a thickness of 2.0 mm. A substance such as petrolatum, with a specific gravity of 0.81 to 0.88, would cover a larger area or provide a thicker layer. This quantity is more than sufficient to provide protectant effect as discussed elsewhere in this document. (See part V. below—Protectants.) Such a quantity would have a total volume of 2 mL, which is also used as a basis for the calculations discussed above for the use of foams. (See part II. paragraph I.4. above—Foams.)

References

(1) "The United States Pharmacopeia," 19th Rev., United States Pharmacopial Convention, Inc., Rockville, MD, p. 704, 1975.

(2) OTC Volume 120022.

4. *Limitation of ingredients in combination products.* The Panel, while recognizing the need for multiple

ingredients in OTC anorectal preparations, concludes that rational therapy dictates that OTC anorectal preparations available to the consumer should contain as few active ingredients as possible at the minimum dosage level recommended by the Panel as safe and effective.

The Panel recognizes that the presence of concurrent anorectal symptoms may justify the use of more than one active ingredient. Thus, there may be several therapeutic goals such as a need to relieve burning, pain, itching, swelling, or to protect the affected area which may be achieved by combining different ingredients in an effective combination. Additionally, the Panel recognizes the need for several types of ingredients for adequate formulation of such combination products. The pharmacologic groups and the ingredients in these groups that will be permitted in a combination will be dependent upon criteria defined elsewhere in this document. Despite the theoretical rationale of a combination of ingredients that relieves several symptoms simultaneously, the Panel concludes that combining ingredients from more than three pharmacologic groups with or without one or more protectants, increases the risks of interactions and of altering effectiveness of the drug product.

The Panel is also aware of the inclusion of inactive, i.e., nontherapeutic, ingredients in anorectal preparations. These inactive ingredients are used in product formulations for various purposes, e.g., preservatives and perfumes. However, the Panel recommends that the safety of inactive ingredients and the advisability of including them in drug products be reviewed by an appropriate body. The Panel briefly discusses inactive ingredients elsewhere in this document. (See part II. paragraph G. above—Bioavailability of Anorectal Dosage Forms and part II. paragraph P. below—Inactive Ingredients.)

In summary, the Panel recommends that OTC anorectal marketed products contain only those active and inactive ingredients that are essential to the product to accomplish its claimed therapeutic effects.

5. *The combination of active ingredients from different pharmacologic groups.* The panel believes that combinations of Category I active ingredients from different pharmacologic groups offer a reasonable means for relieving concurrent symptoms. The Panel can find little scientific justification for including ingredients from more than three pharmacologic groups in the same product.

The Panel concludes that combining more than three Category I active ingredients, each from a different pharmacologic group, with the exception of protectants, would place the combination in Category III. Before such combinations may be classified as Category I, a significant target population requiring such a combination for the treatment of concurrent symptoms must be identified.

The Panel also concludes that, in addition to three Category I active ingredients, each from a different pharmacologic group, a combination may contain not more than four Category I protectants as specified elsewhere in this document. (See part II. paragraph K.6.a. below—Protectants.) This exception for protectants is not inconsistent with the philosophy of exposing the consumer to the least number of drugs because the effectiveness of protectants is primilarily due to passive physical properties, providing a wide margin of safety. Chemically active protectants will be identified when special problems are known to exist or are suspected.

6. *The combination of active ingredients from the same pharmacologic group*—a. *Protectants.* The protectants have been excluded from the general rule that no more than one ingredient from each pharmacologic group be used in a Category I combination. In the past, protectants have been regarded primarily as pharmaceutical necessities, e.g., vehicles and stiffening agents. However, the Panel has recognized that the physical properties of these ingredients are often of therapeutic value in the symptomatic treatment of anorectal symptoms. (See part V. below—Protectants.) The Panel concluded that this concept is reasonable because protectants are, in general, safe for OTC use and require few limitations on dosage. Also the physical manipulation of varying quantities of these ingredients is useful in formulating products of a desired consistency, e.g., ointment or suppository.

Some protectant active ingredients also have other pharmacological activities and consequently have been reviewed by the Panel for more than one claimed effect.

The Panel further concludes that to exert a protective effect and to justify a claim for this drug effect when only one protectant is present, it must be present in a combination in a concentration of at least 50 percent of a dosage unit. For those protectant ingredients limited to concentrations of less than 50 percent, the data indicate such ingredients are usually present in combination with other protectant ingredients. In a combination containing two, but not more than four, protectants, the total concentration of all the protectants in the combination must be at least 50 percent of a dosage unit. This concept was based on the Panel's determination of the minimum concentration of a protectant ingredient in a combination that wold provide a protectant effect (i.e., at least 50 percent of a dosage unit) and still permit the addition of other active ingredients (e.g., 20 percent benzocaine) and still allow for inactive ingredients.

It is reasonable to expect that no more than four different Category I protectants will be needed in any one product. Only four products submitted to the Panel had four or more protectant ingredients.

b. *Topical anesthetics, vasoconstrictors, conterirritants, astringents, wound-healing agents, antiseptics, keratolytics, and anticholinergics.* The Panel is concerned with the marketing of combination products containing more than one active ingredient from these pharmacologic groups. Each Category I combination is currently limited to one Category I active ingredient from any one pharmacologic group except for protectants. The Panel can find little scientific justification for combining more than one active ingredient from the same pharmacologic group in the same combination product.

The Panel believes that to provide for combinations containing ingredients from the same pharmacologic group would contribute to the likelihood of undersirable additive or synergistic effects. Further, to include in a combination product more than one ingredient from the same pharmacologic group is unreasonable because the use of more than one safe and effective active ingredient serves no added benefit nor decreases the risk of toxic effects. It is accepted medical practice to administer only those drugs necessary for the safe and effective treatment of the patient. The Panel believes that this concept should also apply to self-medication using OTC drugs for relief of symptoms without the advice of a physician.

In conclusion, to allow for the possibility, however unlikely, that there may be advantages to combining two ingredients from the same pharmacologic group, each at less than the recommended Category I dosage, the Panel has determined that such combinations be classified as Category

III. Additional studies are needed for Category III combinations to determine their safety and effectiveness. (See part II. paragraph K.10. below—Criteria for Category III combination products for external and/or intrarectal use.) The Panel has futher determined that any combination product containing more than two active ingredients from the same pharmacologic group, e.g., three vasoconstrictors, is irrational and is therefore classified as a Category II combination. There is no reason to expect a possible benefit from the combintion, and exposure to greater numbers of ingredients may increase the risk of adverse reactions, may decrease safety, and/or may produce unpredictable changes in effectiveness.

7. *Labeling of active ingredients.* As discussed above, the Panel has determined that each active ingredient in a combination product must make a contribution to the claimed effects. (See part II. paragraph K.1. above—General combination policy.) If a single ingredient has more than one pharmacologic activity related to use in anorectal disease, these should all be identified in the labeling and be consistent with the pharmacologic activities produced at the recommended dosage for the combination product.

The Panel recommends that the labeling of a combination product containing active ingredients for treatment of concurrent symptoms emphasize the use of the product only when all such symptoms are present. The consumer should be adequately informed by means of the labeling as to the therapeutic capabilities of the product.

8. *Criteria for Category I combination products for external and/or intraectal use.* Based upon an evaluation of the ingredients and the data submitted to the Panel for review, the following criteria have been established:

a. Each active ingredient in a combination must meet the Category I conditions established within this document.

b. Any Category I combination containing only protectants and claiming a protectant activity may contain no more than four protectants, provided the total concentration of protectants are present in at least 50 percent of the dosage unit. Final testing is not required.

c. Any Category I combination claiming a protectant activity may contain no more than four protectants in addition to the specific combinations of Category I ingredients as set forth below, provided the protectants are present in a total concentration of at least 50 percent of a dosage unit, or, when only one protectant is present in a combination claiming a protectant activity, it must be present in a concentration of at least 50 percent of a dosage unit. (See part II. paragraph K.10. below—Criteria for Category III combination products for external and/or intrarectal use.)

d. Products that do not claim protectant activity and contain one Category I active ingredient from each pharmacologic group in the combinations identified below are classified as Category I combination products, provided that (1) the active ingredients and their labeling are generally recognized as safe and effective, (2) such ingredients are present in amounts within the effective dosage range, and (3) the final formulation has been shown to be safe and effective. (See part II. paragraph K.10. below—Criteria for Category III combination products for external and/or intrarectal use.)

9. *Criteria for Category II combination products for external and/or intrarectal use.* a. A combination is Category II if a Category II ingredient or Category II labeling is present in the combination product.

b. If a combination contains an active ingredient or has labeling that has not been reviewed by this Panel, such ingredient or labeling is classified as Category II.

c. A combination product is classified as Category II if it includes more than two active ingredients from the same pharmacologic group, except protectants.

d. If a combination contains five or more active ingredients, excluding protectants, such a combination is classified as Categry II. It is irrational and presents an increased, unacceptable risk of adverse reactions.

e. Specific combinations of certain pharmacologic groups have been determined by the Panel to be unsafe or irrational and classified as Category II.

(1) Any combination containing both a local anesthetic and a counterirritant. The Panel concludes that the simultaneous use of a counterirritant and a local anesthetic comprises a specific combination that is irrational and is therefore not allowed. The mechanism of action of a counterirritant is dependent upon intact nerve function that is specifically blocked by an effective local anesthetic. Although the onset of action of the local anesthetic may be briefly preceded by the action of the counterirritant, this does not constitute a significant justification for the combination.

10. *Criteria for Category III combination products for external and/or intrarectal use.* Based upon an evaluation of the data submitted to the Panel for review, the following criteria and testing procedures are recommended:

a. If a combination product contains not more than three Category I ingredients each from a different pharmacologic group, excluding protectants, and the final formulation has not been tested for safety and effectiveness, the combination is classified as Category III. The following specific combinations of pharmacologic groups, are in Category III.

(1) Combinations containing any single Category I active ingredient and one or more protectants.

(2) Combinations of any two Category I active ingredients, each from a different pharmacologic group listed below, may be combined with or without one, but not more than four, protectants. (See part II. paragraph K.6.a. above—Protectants.)

(i) Combinations containing a local anesthetic and a vasoconstrictor.

(ii) Combinations containing a local anesthetic and an astringent.

(iii) Combinations containing a local anesthetic and a keratolytic.

(iv) Combinations containing a vasoconstrictor and an astringent.

(v) Combinations containing a counterirritant and an astringent.

(vi) Combinations containing a counterirritant and a keratolytic.

(vii) Combinations containing an astringent and a keratolytic.

(3) Combinations of any of the following three Category I active ingredients, each from a different pharmacologic classification, may be combined with or without one, but not more than four, protectants. (See part II. paragraph K.6.a. above—Protectants.)

(i) Combinations containing a local anesthetic, a vasoconstrictor, and an astringent.

(ii) Combinations containing a local anesthetic, astringent, and keratolytic.

(iii) Combinations containing a vasoconstrictor, counterirritant, and astringent.

(iv) Combinations containing a counterirritant, astringent, and keratolytic.

(4) Category III testing: The above Category III combinations must be subjected to testing before they will be allowed on the OTC market. (See part II. paragraph L. below—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

a. If a Category III ingredient or labeling is present in a combination product containing no Category II

ingredient or labeling, the combination is classified as Category III.

b. A combination product is classified as Category III if it contains four Category I active ingredients, each from a different pharmacologic group, except protectants.

Combinations with ingredients representing four pharmacologic groups are more likely to be less safe and effective than three ingredients. It is not reasonable to assume that a target population exists that requires relief of anorectal symptoms by four different mechanisms. In any case the benefit-to-risk ratio decreases to a questionable level.

Category III testing: If, when tested alone, the Category III ingredient can be shown to be safe and effective in accordance with the standards for evaluation in the recommended protocol, the ingredient then qualifies for Category I status. (See part II. paragraph L. below—Criteria and Testing Guidelines for Placing Category III Ingedients, Combinations, and Labeling in Category I.) The combination will then contain only Category I ingredients, but further testing is required to show that the combination in final formulation is safe and effective.

d. A combination product is classified as Category III even if it contains Category I ingredients from different pharmacologic groups when any ingredient or ingredients used to relieve the same symptom are present at less than the minimum effective dose established by the Panel.

Category III testing: For a Category III combination, testing must be carried out to demonstrate (a) safety no less than that of the individual ingredients and (b) a contribution by each ingredient to the effectiveness of the product.

Testing for effectiveness of all anorectal ingredients and combinations in final formulations should demonstrate in clinical trials that there is statistically significant difference in effectiveness of the combination for relief of a symptom as compared to the combination without each of the active ingredients, excluding protectants; e.g., a product composed of active ingredients A, B, C, and D in a vehicle (final formulation) must be compared to control (vehicle plus protectants when present) and the following combinations: (A, B, C), (A, B, D), (B, C, D), and (C, D, A). The combination of other anorectal active ingredients with protectants resulting in unpredictable changes in safety and effectiveness is demonstrated by many investigators (Refs. 1 and 2). For this reason, the formulation of protectants used in testing must be consistently used in each permutation and identified by name and concentration in the monograph. Any change in formulation of protectants used requires retesting.

The exclusion of protectants from testing for relief of irritation, discomfort, burning, itching, or swelling (i.e., Category I claims) does not preclude the need for testing protectants for other claims (Category III), such as zinc oxide when labeled as an astringent.

References

(1) Ritschel, W. A., "Biopharmaceutical Development and Evaluation of Rectal Dosage Forms," *in* "Applied Biopharmaceutics II," College of Pharmacy, University of Cincinnati, Cincinnati, OH, pp. 1153–1207, 1973.

(2) OTC Volume 120072, pp. 5–18.

e. Combinations containing Category III and Category I active ingredients for which the available effectiveness data are insufficient for Panel to make a final determination are classified as Category III and are listed below. Such combinations include Category I and Category III active ingredients on the basis that a theoretical rationale exists for these combinations but safety and effectiveness remains to be established.

(1) Wound-healing agent and local anesthetic.

(2) Wound-healing agent and vasoconstrictor.

(3) Wound-healing agent and astringent.

(4) Wound-healing agent and antiseptic.

(5) Wound-healing agent, local anesthetic, and vasoconstrictor.

(6) Wound-healing agent, local anesthetic, and antiseptic.

(7) Wound-healing agent, vasoconstrictor, and antiseptic.

(8) Wound-healing agent, local anesthetic, and astringent.

(9) Wound-healing agent, vasoconstrictor, and astringent.

(10) Wound-healing agent, astringent, and antiseptic.

(11) Local anesthetic and astringent.

Category III testing: An acceptable testing procedure will be one in which the combination, as well as each individual ingredient of the dose in the combination, and a control (vehicle and protectants when present) are evaluated against the relevant symptoms either in the same study or in separate studies using comparable test protocols. (See part II. paragraph L. below—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.) In this way, comparisons of effectiveness can be made between the combination, the individual active ingredients, and the placebo by external or intrarectal administration. When tested alone by external or intrarectal administration, each individual ingredient should demonstrate a statistically significant effect against the relevant symptom when compared to control (vehicle plus protectants when present).

For the combination of Category I ingredients from different pharmacologic groups to be a Category I combination, the combination must also exert a statistically significant effect against each of the relevant symptoms when compared with the control.

L. *Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I*

1. *General considerations.* The Panel has placed ingredients, combinations, and labeling in Category III because there was insufficient evidence to establish safety and/or effectiveness of the ingredient or combinations when used externally and/or intrarectally for the relief of symptoms associated with anorectal disease. In addition, the Panel concludes that final formulation testing of all ingredients and combinations cannot be avoided.

The Panel has recognized that the testing of a Category III ingredient or combination currently marketed for use in anorectal disorders would necessarily be less rigorous than testing of a new ingredient or combination. This is true, in most cases, because there has been long-term use of the combination products in Category III without any recognized hazard, and it is often necessary to test only one aspect of safety and/or effectiveness for each ingredient or combination. Therefore, rigorous safety testing has been modified to take into account years of human use and experience. Required testing guidelines for all Category III ingredients and combinations are discussed here in general. Specific requirements for each ingredient are identified below and in each individual ingredient section when applicable. A general scheme for evaluation of new anorectal drugs is discussed elsewhere in this document because testing standards adequate to change the classification of Category III ingredients to Category I would not suffice for a new drug entity. The following guidelines pertain to Category III ingredients and combinations of Category I and III ingredients only:

a. *The need for studies in the anorectum.* In all effectiveness studies, the site of study should be the human rectum and anorectal area because of the unique anatomy and physiology of the anorectal area and because the area is frequently traumatized by bowel

movements, ambulation, or pressure while sitting. In addition, the anorectal area is warm and moist because it is usually covered by clothing. These factors make the anorectal area subject to irritation. Other anatomical sites demonstrating the effectiveness of agents for relief of symptoms or for promoting healing are not satisfactory. The Panel has reviewed a variety of clinical studies designed to test the effectiveness of products when used in the human anorectal area (Refs. 1 through 21). These studies confirm both the feasibility of such studies and the availability of patients for such studies. Testing for sensitization and irritation may be done on other skin areas, such as the back or the forearm according to standard tests. (See part II. paragraph L.2.b. below—Safety testing for external use.) Carefully designed trials in humans can simultaneously study allergenicity, local and systemic toxicity, and effectiveness. In most cases safety testing can be conducted on the human anorectal area, but where there is clear concern for systemic toxicity, preliminary animal testing may be necessary.

References

(1) OTC Volume 120003.
(2) OTC Volume 120004.
(3) OTC Volume 120007.
(4) OTC Volume 120008.
(5) OTC Volume 120010.
(6) OTC Volume 120014.
(7) OTC Volume 120015.
(8) OTC Volume 120020.
(9) OTC Volume 120022.
(10) OTC Volume 120023.
(11) OTC Volume 120024.
(12) OTC Volume 120028.
(13) OTC Volume 120030.
(14) OTC Volume 120031.
(15) OTC Volume 120035.
(16) OTC Volume 120037.
(17) OTC Volume 120059.
(18) OTC Volume 120063.
(19) OTC Volume 120065.
(20) OTC Volume 120075.
(21) OTC Volume 120067.

b. *The vehicle as a control.* The ingredient or ingredients should be tested in the vehicle in which they are to be commercially formulated. This requirement is of prime importance because of the complex effects the vehicle may have on ingredient activity and absorption, as discussed elsewhere in this document. (See part II. paragraph G. above—Bioavailability of Anorectal Dosage Forms.) An important example of the effects of vehicle on ingredients is discussed by the Advisory Review Panel on OTC Antimicrobial Drug Products in their evaluation of iodine as an antimicrobial agent as published in the Federal Register of September 13, 1974 (39 FR 33103 at page 33129) in which the Panel concludes that the amount of free elemental iodine is an inverse function of complexation with the vehicle which decreases toxicity and effectiveness.

c. *Double-blind studies.* The effectiveness of the ingredient must be tested in human subjects with anorectal disease using a controlled double-blind study. Double-blind trials are necessary because of the extreme variability of the pathology, the course and symptomatology of anorectal disease, and also because of the difficulty in establishing adequte objective methods of assessment. A double-blind trial is best suited for this type of situation because these variables are controlled.

Double-blind trials permit a reasonable basis for assessment of symptomatic relief, which is the primary purpose for using OTC anorectal ingredients. Assessment of symptomatic relief shall be done by questionnaires. Pathology may be evaluated by use of photography and/or biopsy and/or physician evaluation. Biopsy may only be appropriate in certain circumstances. Ideally, clinical trials should include the following groups: (1) A final formulation, including protectants when present, with any ancillary measures specified in the protocol; (2) the vehicle, including protectants when present, without other active ingredients but with any ancillary measures specified in the protocol; (3) ancillary measures only; and (4) no treatment.

Because of the usual progression in the healing of benign anorectal ailments, a crossover design study would not be satisfactory. Therefore, only the first two groups above ((1) and (2)) could be studied in double-blind fashion. Data on the remaining two groups above ((3) and (4)) are very useful, but once established provide a valuable baseline for proof of effectiveness.

Demonstration of statistically significant relief of the symptoms of burning, pain, or itch, and/or resolution of anorectal swelling of hemorrhoids or anorectal tissue as shown by photography and/or biopsy and/or physician evaluation in such trials would provide adequate proof of effectiveness.

The feasibility of double-blind studies of anorectal products in the human has been previously demonstrated in several studies presented to the Panel. Further, a recent, detailed double-blind protocol for thorough testing of anorectal products using some of these anorectal ingredients and other ingredients has also been submitted to FDA (Ref. 1).

Reference.

(1) OTC Volume 120071.

d. *Dose and frequency.* When testing for effectiveness in humans, the ingredient should be applied in doses and in a dosage frequency that is reasonable comparable to actual OTC use. For safety testing, the ingredient should be applied in doses and at frequencies that are twice those used OTC because the Panel recognizes the occasional tendency to overuse anorectal products. It has been shown in studies of intrarectal creams and ointments that an average of 2 g of cream or ointment is used per application (Ref. 1) and that the average suppository weighs 2 g (Ref. 2). The usual number of daily applications is three to four. Therefore, human testing should be carried out for a minimum of 7 days using 2 g four and eight times daily and 4 g four and eight times daily. This regimen will, therefore, test usages of twice and four times the recommended amount. When the ingredient is to be applied intrarectally, the ingredient and the control vehicle must be applied in a quantitative manner by use of a pile pipe or suppository. When applied externally, the ingredient must also be applied in a specified and measured quantity.

References

(1) OTC Volume 120022.
(2) "The United States Pharmacopeia," 19th Rev., The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 704, 1975.

e. *Assessment of subjective and pharmacologic effects.* Testing shall be carried out in patients receiving a final formulation versus control to prove symptomatic relief. For subjective assessment, the use of a questionnaire shall be adequate to demonstrate statistically significant symptomatic improvement, and would be acceptable for proof of claims of symptomatic relief.

The exact format of a questionnaire, in the opinion of the Panel, does not need to be included here, nor does it seem appropriate to do so. A number of studies submitted included variations that could serve as possible models for such a questionnaire (Ref. 1). A standard form should be developed by FDA with the help of interested individuals which will provide a uniform basis for evaluation of improvement in the symptoms of burning, pain, itch, swelling (as in hemorrhoids and/or hemorrhoidal tissue) and discomfort due to these symptoms.

Although the Panel has approved many ingredients on the basis of specific pharmacological activities (anesthesia, counterirritation, or vasoconstriction) demonstrated at other sites in the body, studies demonstrating these specific activities must be performed in the

anorectal area and at the same concentration and formulation to prove each claim relating to these activities. The effects of such anorectal ingredients are being measured in terms of specific pharmacologic action and/or the general anorectal symptoms.

Reference

(1) OTC Volume 120071.

f. *Statistically significant results*—(1) *General safety considerations.* Because of the considerable differences in the two general areas of application of an anorectal product, i.e., inside and outside the rectum, the safety of these products has been considered on both sites. (See part II. paragraph L.2. below—Safety testing.) Thus, the safety of a product applied intrarectally will relate to its effects on, and absorption across, the mucous membrane lining the rectum. The safety of an externally applied product will relate to its application to normal and inflamed epithelium of the anal canal and perianal area.

All tests for safety shall be carried out using an adequate number of trials in animals or humans to allow adequate statistical analysis, and the results must be statistically significant to be acceptable.

(2) *General effectiveness considerations.* The spectrum of anorectal pathology is broad, but these conditions usually cause a narrow range of complaints due to irritation of sensory nerve endings in the area. This results in, depending on the degree of irritation, burning or pain with or without defecation, tenesmus, or the repeated sensation of the need to defecate, and pruritus or itching of the anal canal and perianal area. Swelling of hemorrhoidal vessels and tissues, which occur for various reasons, are frequently part of the anorectal pathology.

Effectiveness of anorectal products shall be evaluated on the basis of their ability to provide relief of symptoms and/or to produce objective improvement in anorectal pathology within the recommended dosage and frequency.

(i) *Relief of symptoms.* Agents acting to alleviate symptoms act by one of several mechanisms: (*a*) Blockade of sensory nerve sensation, as with local anesthetics; (*b*) production of sensation of a different character, e.g., cooling, which distracts from the original sensation, e.g., pain, as with counterirritants; or (*c*) decreased swelling of affected areas such as hemorrhoids and hemorrhoidal tissues, as theoretically occurs with vasoconstrictors.

It is important to note that agents providing relief by the first two mechanisms, local anesthesia and counterirritation, can only act in external areas (perianal) supplied by sensory nerves, below the anorectal line. However, it has been argued that effects of these agents on the automatic nerves above the anorectal line may provide relief of symptoms as reported in studies with some anorectal ingredients (Ref. 1). Therefore, demonstration of statistically significant relief of symptoms after one or more intrarectal applications, and the duration of effect in two double-blind studies of the ingredient as finally formulated would constitute proof of its effectiveness when performed by separate investigators. Other specific aspects of effectiveness are discussed elsewhere in this document. (See part II. paragraph L.3. below—Testing for effectiveness.)

Essentially no clinical data exist to demonstrate the actual validity of these mechanisms in relieving anorectal symptoms. The Panel has concluded that studies for effectiveness of anorectal ingredients which are performed on other body sites cannot be extrapolated as effective in relieving anorectal symptoms because there is a valid impediment. For example, the lack of pain receptors in the rectum in evaluating local anesthetics and the unique anatomy of swollen hemorrhoidal tissue require specific studies.

The Panel has defined prompt or immediate relief of symptoms as those effects that occur within 20 minutes after application of an anorectal product and have a duration of effect as established by appropriate studies.

(ii) *Other aspects of relief of symptoms.* The Panel concludes that some ingredients and ancillary measures, such as frequent warm water baths (sitz baths), regular cleansing of the anorectal area, although not particularly effective in providing more immediate symptomatic relief, will provide relief within 7 days or less by providing better conditions for healing of the anorectal area, or possibly, actually promoting more rapid healing of the area, and thus secondarily relieving symptoms over a period of time. This effect may occur through several mechanisms.

(*a*) *Maintenance of relative cleanliness or decreased bacterial contamination of the anorectal area.* The Panel concludes that although complete antisepsis in this area cannot be maintained, it is generally recognized that healing is more likely to occur in a relatively clean area. This is accomplished by sitting in sitz baths and/or by washing with soap and water, and careful rinsing of soap. Antiseptics may reduce microbial flora in the anorectal area, but further studies are necessary to show that antiseptics are more effective than soap and water.

(*b*) *Debridement of the affected area.* Certain agents such as keratolytics, as well as soap and water, will remove the necrotic or irritated dead skin cells and thus provide better conditions for regrowth of normal tissue. Such an action is generally believed to allow normal healing and, consequently, relief of one or more anorectal symptoms. Keratolytics are discussed in more detail elsewhere in this document. (See part X. below—Keratolytics.)

(*c*) *Promotion of healing.* It is proposed by several investigators that certain agents may actually stimulate healing in a wounded or inflamed area so that repair is more rapid than normal (Ref. 2). This matter is discussed elsewhere in this document. (See part VIII. paragraph A. below—General Discussion.)

Claims for relief may include the specific pharmacologic group by which an agent provides relief, e.g., local anesthesia, or they may be less specific by claiming that they provide relief of burning, pain, itch, or swelling, except that to be able to make specific claims, such as promoting antisepsis of the anorectal area or healing, evidence of such effects must be produced in addition to general demonstration of relief. If no such claim is desired, demonstration of relief by methods described elsewhere in this document will provide for elevating an ingredient to Category I for relief of symptoms only. (See part II. paragraph L.1. above—Assessment of subjective and pharmacoligic effects.)

References

(1) OTC Volumes 120010 and 120011.

(2) OTC Volumes 120007, 120008, 120009, 120021, 120032, 120060, 120061, 120062, 120069, and 120082.

2. *Safety testing.* A general protocol for testing the safety of anorectal products must be divided into local effects on the skin and mucous membranes, systemic effects of the agency when absorbed from specific dosage forms and formulations, effects to be evaluated on the intact surface as opposed to the inflamed or excoriated surface, the allergy-producing potential through local or systemic routes, and acute and chronic toxicity testing on skin, mucous membranes, and/or specific organs when the ingredient is determined to have systemic effects. A scheme outlining a general protocol for

testing the safety of anorectal products is presented below.

Ingredients in Category III need not be tested at the recommended dosage level for local and systemic safety in animals, in view of their years of use, except when special problems have been identified in the discussion of specific ingredients in this document.

If prior toxicity studies at ten times the concentration recommended for the proposed use of the ingredient have demonstrated a hazard in two species of animals, safety testing must be conducted at the amount and concentration recommended for the proposed use as well as at twice the amount in the same concentration, to allow an estimation of the safety margin in humans. Because of long-standing OTC use without reported toxicity, vigorous animal testing of the ingredient will not usually be necessary except when specified. If significant toxicity is encountered with the higher amount, the ingredient will not be allowed for use at the proposed concentration, and further testing of the ingredient for the specific margin of safety and effectiveness at a lower concentration must be conducted.

Proof of safety is to be determined in humans according to site of use, i.e., intrarectal or external. Testing should include acute and chronic toxicity studies only where the ingredient has been placed in Category III for reasons of safety.

a. *Safety testing for intrarectal use*—(1) *Systemic toxicity.* Some compounds used in OTC anorectal products have been shown to be absorbed when applied intrarectally (Refs. 1 and 2). Compounds for intrarectal use placed in Category III for reasons of safety must be tested for potential systemic absorption from the rectum. Assessment of the absorption shall be made by blood level determinations, or if this is not feasible, by urinalysis and/or physiological measurements. Any ingredient that is shown to be absorbed and that has known direct pharmacologic effects, such as a potential change in vital signs, must have these effects measured simultaneously with blood level measurements. These studies must also include measurements of liver, renal, and hematologic function following exposure to the drug.

When systemic absorption occurs from the rectal mucosa, additional animal studies will be required and reviewed before elevation to Category I. These additional animal studies include (i) carcinogenicity studies where the ingredient resembles known carcinogens or co-carcinogens, (ii) mutagenicity and teratogenicity studies that are of primary importance owing to the frequent use of hemorrhoidal agents in pregnant women, and (iii) pharmacokinetic studies in which the minimal requirement is the demonstration of the half-life of the ingredient and of any major metabolites to demonstrate lack of accumulation in the body.

(2) *Local toxicity.* Testing of the ingredients for rectal irritation shall be done on normal human volunteers and normal rectal mucosa. Assessment may be done by either anoscopic or proctosigmoidoscopic examination and the use of photography and/or a clinical grading system. Assessment can also be carried out by rectal biopsy. If there is significant concern regarding irritancy, these studies may be preceded by conventional patch testing at other body sites in humans or by testing in the rectal area of animals (Ref. 3). However, final proof of lack of irritancy must be made in the human rectum. This is feasible as a part of other clinical studies of the product using a 0 to 3 grading system for patch testing in which 0 is no reaction, 1 is mild erythema, 2 is moderate erythema without exudation, and 3 is severe erythema, exudation, and blistering. If irritation occurs in more than 5 percent of the subjects with an average of less than 2, a warning would be required in the labeling of the product to alert the consumer to the possibility of irritation, as, for example, occurs with resorcinol, but this would not prevent its elevation to Category I. The presence of moderate irritation, e.g., an average of 2 or greater in more than 5 percent of the subjects, would automatically move the ingredient at that dose or concentration to Category II.

The Panel will not require testing for the occurrence of rectal sensitization because allergic reactions on mucous membranes do not appear to be a problem.

b. *Safety testing for external use*—(1) *Systemic toxicity.* The Panel recognizes that there is some potential systemic absorption of ingredients through inflamed perianal and anal canal skin. However, the Panel does not believe this is of sufficient significance to require systemic toxicity testing.

(2) *Local tocicity*—(i) *Irritation.* Some ingredients used in OTC anorectal products may produce significant local irritation with either acute or repeated use. Because these products have long-standing human use with few reports of irritation, studies may be limited to human subjects. Irritation in human subjects may be assessed on the abraded skin, or by patch testing in the anorectal area or on the back. If any irritation occurs on the back (1 or greater) in more than 5 percent of the subjects, studies must then be conducted in the anal canal and perianal area to show lack of similar irritation to move a Category III ingredient to Category I. If less than moderate (average of less than 2) irritation is demonstrated in the anorectal area, this would require a warning in the labeling of the product. If moderate (an average of 2 or greater) irritation occurs in more than 5 percent of subjects, the ingredient will automatically become Category II.

(ii) *Sensitization.* Several ingredients in Category III have known allergenic properties. For these ingredients, where concern about allergenicity is part of the concern about safety, testing should be carried out by standard techniques as described by Draize (Ref. 4) or other standard sensitization tests (Ref. 3).

In clinical trials, no fewer than 200 individuals should be used for estimation of allergenicity. The Panel concludes that an incidence of greater than 3 percent of allergic reactions in a random population, or 10 percent in a dermatologic clinic population in such trials, would place the ingredient in Category II.

References

(1) OTC Volumes 120010 and 120011.

(2) OTC Volume 120027.

(3) Marzulli, F. N. and H. I. Maibach, "Contact Allergy: Predictive Testing in Man," *Contact Dermatitis*, 2:1–17, 1976.

(4) Draize, J. H., G. Woodard and H. O. Calvery, "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," *Journal of Pharmacology and Experimental Therapeutics*, 82:377–390, 1944.

3. *Testing for effectiveness.* To elevate an ingredient from Category III to Category I, one of two following effects must be shown:

(1) *Immediate relief of symptoms.* Certain ingredients, such as the local anesthetics and counterirritants, can produce relief of burning, pain, or itching shortly (within 20 minutes) after application. This effect can only be assessed by carefully controlled, double-blind tests of subjective effects in humans with anorectal symptoms. Demonstration of statistically significant relief of discomfort due to burning, pain, itch, or swelling within 20 minutes is sufficient to establish effectiveness. Claims for immediate relief are permitted when testing has been done to prove such relief.

(2) *Relief of burning, pain, itching, or swelling with repeated application.* The Panel recognizes that certain agents, such as protectants, astringents, keratolytics, and wound-healing agents

may provide relief when used after repeated applications over a period of days. The Panel will only consider effects occurring within 7 days, because use beyond this time indicates the need for a physician's evaluation. Clinical studies to prove effectiveness of this type of ingredient must provide statistically significant relief of symptoms greater than control within 7 days.

Claims that specify the time required for the onset and the duration of the relief of symptoms and/or specify the mechanism of action must be substantiated by appropriate testing.

Proof of effectiveness is to be determined in double-blind studies on humans according to site of use, i.e., intrarectal or external, and the duration of treatment. The human subjects must have anorectal disease and associated symptoms.

(i) *Effectiveness testing for intrarectal use.* To provide evidence for relief of symptoms, double-blind tests should be carried out in patients using active ingredients in final formulation versus control (vehicle, with protectants when present). The final formulation must be administered intrarectally only by use of a suppository, pile pipe, or other method that allows quantitative measure. The assessment of relief must be based on subjective and/or objective responses from the consumer by use of a properly designed questionnaire. In addition, a screening technique as proposed by Adriani and Zepernick (Ref. 1) and Riegelman (Ref. 2) may be developed into an objective protocol capable of completion in a short period of time. The technique utilizes blockage of a minute electrical stimulation to skin after application of ingredients to be tested.

Criteria for effectiveness after repeated applications include both symptomatic relief and, optionally, reversal of pathological changes within 7 days.

Relief may occur after repeated applications in the intrarectal area. This theoretically will occur only when pathological changes are reversed. Therefore, relief must be demonstrated by either subjective assessment by questionnaire and/or optionally by objective proof that pathological changes have been reversed.

The definitive proof for reversal of pathological change must be carried out in the human anorectal area by demonstrating clinically accelerated healing of a defined anorectal lesion by biopsy, photography, or clinical assessment in double-blind trials comparing the final formulation with control. Demonstrating this property at other anatomical sites is not adequate to support a claim for effectiveness in the unique anatomical area of the anorectum. A claim specifying wound healing as the mechanism of action of an ingredient can only be made on the basis of appropriate studies, but a claim without reference to the mechanism of action could be made for relief of anorectal symptoms after repeated applications if anorectal studies have demonstrated this.

(ii) *Effectiveness testing for external use.* To provide evidence for relief of symptoms, testing should be carried out as described in paragraph (i) above. Because the endpoint of testing is subjective relief, the only difference in testing design is a dosage form for external use and the site of application.

Criteria for effectiveness include both symptomatic relief after repeated application and the reversal of pathologic changes, such as decrease in inflammation. The relief of symptoms must be demonstrated whether the objective reversal of pathological changes occur or not.

Relief after repeated external application may occur as a result of one or more mechanisms, such as local anesthetics, wound healing, astringency, keratolysis and antisepsis. Evidence of symptomatic relief may be assessed by an appropriately designed questionnaire that does not require that a physician evaluate symptomatic relief.

References

(1) Adriani, J. and R. Zepernick, "Clinical Effectiveness of Drugs Used for Topical Anesthesia," *Journal of the American Medical Association*, 188:711–716, 1964.

(2) Riegelman, R. H., "An Objective Method for the Evaluation of Topical Anesthesia in the Anorectal Area," *American Journal of Proctology*, 17:402–404, 1966.

4. *Testing for specific claims.* To prove specific claims for wound healing, keratolysis, astringency, and antisepsis, testing must be carried out. However, statistical proof of clinical subjective relief after repeated application must be demonstrated in all cases; this requirement exists to preclude the use of single doses to establish effectiveness.

a. *Wound healing.* (See part VIII. paragraph C. below—Data required for evaluation.)

b. *Keratolysis.* Proof of keratolytic activity by an ingredient in the anorectal area would be difficult to demonstrate except by use of biopsy of the affected skin before and after use of the ingredient. Therefore, such testing may be performed on other body sites. If testing done on other body sites demonstrated clear desquamation of epithelium and necrotic tissue by histological examination (which is feasible), a claim for keratolysis could be made for the ingredient, but the ingredient must be shown to provide symptomatic relief in human double-blind testing.

c. *Antisepsis.* (See part IX. paragraph C. below—Data Required for Evaluation.)

d. *Astringency.* The property of astringency is a variably defined one for which no specific testing methods for effectiveness have been developed. If a claim for such an effect is desired, the method for proof of the effect will be evaluated by FDA at the time of submission.

M. The Pharmacist as a Direct Contributor to Medical Care

The Panel is aware of the current policy as established by the Commissioner in the Federal Register of June 4, 1974 (39 FR 19880) which does not presently permit the use of the term "pharmacist" on OTC drug labeling. However, the pharmacist is an integral part of consumer education and deserves to be recognized as a readily available source of drug information.

N. The Use of Anorectal Drugs During Pregnancy and by Nursing Mothers

The incidence of hemorrhoids is relatively high during pregnancy partly due to the compression of the major vessels in the anorectal area during this condition. No studies on the use of the anorectal drugs in pregnant women were found. However, the Panel considered several basic factors for formulating a recommendation for the use of anorectal drugs in pregnant women: (1) Because of the extreme complexity of the subject of teratogenesis (Refs. 1 and 2), drug effects on the fetus (Refs. 3 and 4), and the difficulty in demonstrating these effects, coupled with the emerging information that a number of drugs, i.e., thalidomide, certain anticonvulsants, and tetracycline do appear to have these effects, it has been generally accepted that only essential drugs be used in the pregnant woman or the nursing mother.

(2) The major concern regarding the use of anorectal drugs in this group relates to the potential for systemic absorption and thus fetal exposure or exposure of the newborn with its immature protective systems. Although data are lacking, the Panel has concluded that systemic absorption of drugs is usually of significant concern only when agents are applied intrarectally. Therefore, concern relates only to those agents available for intrarectal use.

(3) The only drugs used intrarectally of concern are those which have a

potential for being absorbed through mucous membranes. Anorectal agents designated as Category I protectants that have no other pharmacologic activity are, as a class (e.g., petrolatum), generally not absorbed significantly, and thus would be acceptable.

On the basis of these considerations, the Panel makes the following recommendations regarding the use of anorectal products in pregnant and nursing women:

(1) Any ingredient that is in Category I for external anorectal use may be used by pregnant and nursing women.

(2) Any ingredient that is a Category I protectant that has no additional pharmacologic effect may be used intrarectally by pregnant and nursing women.

(3) All intrarectal ingredients, except those Category I protectants that have no additional pharmacologic effect, must carry a warning: "The safety of this product has not been established for use by pregnant women or by nursing mothers," (See part II. paragraph Q.5. below—Warnings.)

References

(1) Meester, W. D., "The Effects on the Fetus of Drugs Given During Pregnancy," *Marquette Medical Review*, 30:147–154, 1964.

(2) Tuchmann-Duplessis, H., "Embryonic Clinical Pharmacology," *in* "Drug Treatment. Principles of Practice of Clinical Pharmacology and Therapeutics," Edited by Avery, G. S., Publishing Sciences Group, Inc., Actin, MA, pp. 44–56, 1976.

(3) Singh, S. and B. L. Mirkin, "Fetal Clinical Pharmacology," *in* "Drug Treatment. Principles of Practice of Clinical Pharmacology and Therapeutics," Edited by Avery, G. S., Publishing Sciences Group, Inc., Actin, MA, pp. 57–70, 1976.

(4) Boreus, L. O., "Fetal Pharmacology," Raven Press, New York, 1973.

O. Pediatric Dosage

The Panel concludes that the safety of protectants and astringents would not preclude their use in the pediatric age group between 2 and 12 years at the same dose level as approved for adults. However, the Panel has concluded that studies of all other anorectal drugs, in the pediatric age group are negligible or non-existent. Therefore, anorectal drugs other than protectants and astringents should not be used in children under 12 years of age, except on advice of a physician, until studies are done to show safety and effectiveness at specific dose levels for children according to measurable parameters such as body weight.

The Panel is also aware that pediatric patients do not comprise a substantial proportion of the patients who receive these OTC products. Chronic constipation, fecal impaction, and straining on elimination of the stool do not lead to hemorrhoids in children nearly as frequently as they do in adults (Ref. 1). Although anal fissures and rectal prolapse are not uncommon, hemorrhoids are, on the other hand, less common in infants and children (Ref. 1).

Frequently, children are diagnosed by their parents and perhaps by physicians to have hemorrhoids when in fact the symptoms may be due to conditions such as rectal prolapse, parasitic conditions, and a variety of congenital disorders such as cystic fibrosis and megacolon (Refs. 2 and 3). Hemorrhoids, when seen in children, may be due to some underlying and often serious cause such as vena caval or mesenteric obstruction, cirrhosis, portal hypertension associated with liver disease, or other causes resulting in venous obstruction (Refs. 1 and 2). Hemorrhoids in children usually subside without surgery when the primary condition is corrected (Ref. 1). However, OTC anorectal preparations have been used on occasion for symptomatic relief (Refs. 1, 2, and 3).

The use of anorectal ingredients other than protectants and astringents in children 2 to 12 years is not appropriate in view of the multiplicity of such severe signs and symptoms, except under a doctor's supervision with treatment directed at the primary cause (Ref. 2).

In summary, the Panel concludes that most anorectal disorders in children are brought to a physician for evaluation and treatment. Thus, there is no target population in children for OTC anorectal products that contain other than protectants and/or astringents. (See part II. paragraph Q.5 below—Warnings.)

References

(1) Letter to DeCillis, T. D. from J. M. Arena is included in OTC Volume 120051.

(2) Letter to DeCillis, T. D. from H.F. Eichenwald is included in OTC Volume 120051.

(3) Letter to DeCillis, T. D. from C. R. Angle is included in OTC Volume 120051.

P. Inactive Ingredients

A variety of inactive ingredients (pharmaceutic necessities) are used in the manufacture and formulation of anorectal products. These inactive ingredients are intended for a variety of purposes such as aromatics, vehicles, or colorants.

For various reasons, individuals may wish or need to avoid using certain inactive ingredients found in OTC drug products. These reasons may include allergic reactions, idiosyncratic responses, fear of safety (whether valid or not), or personal dislike. It is impossible to make a free choice in this regard unless the full contents of drug products are listed in the labeling. The Panel is aware that the Federal Food, Drug, and Cosmetic Act does not require the labeling of inactive ingredients if none of the inactive ingredients are identified in the general conditions for use and labeling of inactive ingredients as published in the Federal Register of April 12, 1977 (42 FR 19156). This notice also indicates that if one inactive ingredient is identified, all such ingredients must be identified in type size one-half of that used for active ingredients. However, for the reasons noted above, this Panel strongly recommends full ingredient labeling of inactive as well as active ingredients for all drug products. (See part II. paragraph Q. below—Labeling.) In support of this position the Panel notes that labeling and composition regulations for food and food products, as published in the Federal Register of October 19, 1976 (41 FR 46156), and cosmetics labeling in accordance with Part 701 (21 CFR Part 701) are already requiring such labeling. Because the purpose of an OTC drug is to alleviate symptoms, it would seem much more compelling to have inactive ingredient information on all OTC drugs. The Panel reaffirms the FDA proposal on inactive ingredients, as published in the Federal Register of April 12, 1977 (42 FR 19156), that marketed products should contain only those ingredients essential to the product. Therefore, the Panel concludes that the consumer should be exposed to the least number of ingredients possible.

The Panel recognizes that several inactive ingredients may be required for the formulation of products and that certain of these inactive ingredients may affect the safety and effectiveness of an active ingredient. (See part II. paragraph G. above—Bioavailability of Anorectal Dosage Forms.) In addition, certain ingredients may serve both functions, i.e., as an active and as an inactive ingredient; petrolatum, for example, can act as a protectant or as a vehicle for active ingredients. Perfumes are known sensitizing agents and the risk of adverse reactions increases with each perfume present.

The Panel concludes that pharmaceutical necessities should be included in the labeling. When perfumes are included in anorectal products, the following warning is required: "If redness, burning, itching, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician." (See Part II. paragraph Q.2.d. below—Warning for anorectal products containing perfume.)

The Panel has reviewed the available literature and submitted data regarding the safety of many of the inactive ingredients contained in anorectal preparations. It is the view of the Panel, however, that the final decisions concerning and the safety and advisability of including these inactive ingredients in drug products be reviewed by an appropriate body. Because many of these ingredients are used in the formulation of many drug products, it is not appropriate that they be dealt with specifically and solely in relation to anorectal products.

The Panel has reviewed the inactive ingredients present in the data submitted to the Panel and complete statements on certain inactive ingredients were prepared which have been appended to the Panel's minutes and are available from the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

The Panel wishes to alert those interested individuals of the Panel's concerns regarding the safety of the following inactive ingredients: Eucalyptus oil, sodium lauryl sulfate, tyloxapol, benzyl benzoate, and perfumes. There are data to suggest that the safety of these ingredients especially merit further study by an appropriate review panel.

Q. Labeling

1. *General comment.* The panel has established three distinct types of labeling for anorectal ingredients, i.e., general labeling, labeling for each pharmacologic group, and individual active ingredient labeling. The labeling discussed in this section is of a general nature and is applicable to the anorectal active ingredients in all pharmacologic groups discussed within this document. The Panel has also recommended specific labeling for each pharmacologic group of ingredients, and that labeling is applicable to each ingredient within that pharmacologic group. Furthermore, in some cases, the Panel has recommended specific labeling for an individual active ingredient and such labeling is applicable only to that ingredient.

Terms such as "greaseless," "stainless," and "vanishing" are intended to provide useful information to the consumer. However, the Panel concludes that such terms are descriptive and not indications for use. These terms must clearly be separated from drug claims made in labeling.

The Panel has accepted the OTC drug review labeling standard as set forth in 21 CFR 330.10(a)(4)(v) which requires that:

> Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.

The Panel concurs with the above labeling requirement as well as the following statement of identity as set forth in 21 CFR 201.61(b):

> Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s) in terms that are meaningful to the layman. * * *

In most cases, the pharmacologic activity of the ingredients reviewed in this document has been demonstrated in body sites other than the anorectal area. However, OTC anorectal ingredients may share a common action in that they relieve the symptoms of pain, itching, burning, and/or swelling, but the pharmacologic activity of many of these active ingredients has not been proved in the anorectal area. It is the opinion of the Panel that consumers will be unable to understand labeling that identifies an anorectal product only by its pharmacologic activity, e.g., local anesthesia. However, they could readily understand an anorectal product that is labeled for its intended use and will provide symptomatic relief. For example, the consumer can understand labeling that says an anorectal product will relieve pain, burning, and itching better than labeling that would identify the anorectal product as a local anesthetic.

For this reason, the Panel has concluded that anorectal ingredients and combinations shall be labeled in terms of the intended use of the product, that is, for the relief of anorectal symptoms such as pain, burning, and itching. Further, the Panel concludes that all ingredients and combinations of such ingredients considered within this document shall be designated as "anorectal agents" or "anorectal products" to reflect the intended use of the ingredient or combination of such ingredients so that consumers will know exactly the intended use of the product. Anorectal agents may include any Category I active ingredient for the relief of symptoms, such as pain, burning, itch, or swelling, which are identified in this document by their usual, respective pharmacologic classifications, e.g., local anesthetics, vasoconstrictors, protectants, counterirritants, keratolytics, and astringents. The Panel has used the traditional pharmacologic classifications only to establish a logical grouping of the ingredients for discussion in this document but has placed the use of specific pharmacologic classifications as labeling claims in Category III until such pharmacologic activity can be proven in the anorectal area. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.) If such pharmacologic activity can be proven in the anorectal area, the product can also be identified by its specific pharmacological activity, but this does not exclude the requirement for product designation as an anorectal agent or anorectal product.

2. *General principles and recommendation.* In addition to the specific labeling recommendations listed in the individual ingredient statements contained within this document, the Panel concludes that the following general principles and recommendations also apply for truthful and accurate labeling:

a. *Labeling of anorectal products.* The labeling of every marketed anorectal product shall be clearly designated as an "anorectal" product to reflect the product's intended use, in addition to a statement of indication such as, "For the temporary relief of discomfort associated with hemorrhoids and other anorectal disorders." (See part II. paragraph Q.4. below—Indications.)

When the product is intended for use on concurrent symptoms, the symptoms must be specified.

b. *Quantitative active and inactive ingredient listing.* The Panel is aware that current regulation only requires the listing of active ingredients and does not require quantitative or inactive ingredient labeling. However, the Panel recommends the following: (1) A quantitative listing of each active ingredient in an anorectal product should be indicated in the labeling. The concentration of each active ingredient should be given per suppository, applicatorful, or other unit of dose.

(2) All inactive ingredients in an anorectal product should be listed in the labeling by their established names and adhere to the proposed inactive ingredient regulation as published in the Federal Register of April 12, 1977 (42 FR 19156).

c. *Directions for use for all anorectal products.* The labeling of all anorectal products must contain the following information as indicated under the heading "Directions for use": Recommended or usual dosage, frequency of administration (e.g., every 4 hours, three times daily), and site of administration (i.e., external or intrarectal application).

Panel members have continually emphasized the importance of anal hygiene. This is essential in achieving symptomatic improvement of anorectal disorders; therefore, the Panel recommends the inclusion of the following directions for use on the labeling of all anorectal products, "When practical, wash the anorectal area with mild soap and warm water and rinse off all soap before application of this product."

d. *Warning for anorectal products containing perfume.* When perfume is included in anorectal products, the following warning is required: "If redness, burning, itching, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician." (See part II. paragraph P. above—Inactive Ingredients.)

3. *Directions for use for specific anorectal dosage forms.* The Panel also recommends the following specific labeling for the various anorectal dosage forms, as indicated for specific anorectal products under the heading "Directions for Use."

a. *External Use*—(1) *For products that are ointments, pastes, creams, jellies, foams, or gels.* "Apply externally to the anorectal area."

(2) *For products that are pads containing anorectal ingredients.* "Gently apply by patting and then discard."

(3) *For products that are ointments, pastes, creams, jellies, foams, pads, or gels for external use only.* "For external use only."

b. *Intrarectal use*—(1) *For products that are wrapped suppositories for insertion into the rectum.* "Remove wrapper before inserting into the rectum."

(2) *For all products to be inserted into the rectum.* "For use by insertion into the rectum."

(3) *For products that are to be used with special applicators such as pile pipes or other mechanical devices.* "Gently insert applicator into the rectum."

c. *External and intrarectal use.* Many anorectal products may be used externally as well as intrarectally. Whenever a manufacturer markets a product for both external and intrarectal use, the following labeling must appear on the product and clearly separate each set of directions under the headings, "For external use" and "For intrarectal use":

(1) *For external use—For products that are ointments, pastes, creams, jellies, foams, or gels.* "Apply externally to the anorectal area."

(2) *"For intrarectal use*—(i) *For products that are to be used with special applicators such as pile pipes or other mechanical devices.* "Gently insert applicator into the rectum."

(ii) *For all products to be inserted into the rectum.* "For use by inertion into the rectum."

4. *Indications.* The Panel accepts the following indications as general labeling for anorectal products in addition to specific labeling appropriate for specific ingredients, as discussed later in this document.

a. "For the temporary relief of the discomfort associated with hemorrhoids and other anorectal disorders."

b. "For the temporary relief of itching associated with hemorrhoids and other anorectal disorders."

c. "For the temporary relief of anorectal itching."

d. "For the temporary relief of local itching associated with inflamed hemorrhoidal tissues."

e. "For the temporary relief from the itching and discomfort associated with hemorrhoids and other anorectal disorders."

f. "For the temporary relief of the discomforts associated with piles (hemorrhoids) and other anorectal disorders."

g. "For the temporary relief of symptoms of anorectal disorders."

h. "Gives temporary relief of anorectal itching."

i. "Temporary relief of itching discomfort associated with hemorrhoids and other anorectal disorders."

j. "For the temporary relief of symptoms associated with hemorrhoids and other anorectal disorders."

k. "To temporarily soothe local discomfort associated with hemorrhoids and other anorectal disorders."

1. "To help relieve the discomfort associated with hemorrhoids and other anorectal disorders."

m. "For the temporary relief of itching."

n. "For the temporary relief of symptoms of inflammation associated with hemorrhoidal tissues."

o. "Gives temporary relief due to external hemorrhoids and other anorectal disorders."

p. "For the temporary relief of pruritus ani."

5. *Warnings.* The Panel is aware that some of the recommendations discussed in this section are not required under the current OTC regulations. However, the Panel wishes to make the following statement: Warning statements may be combined to eliminate the duplication of words or phrases, but the combined warning statement must be clear and understandable with no decrease in meaning and emphasis. Warning statements must be included on the container and the package in a "box border"; they should be printed in black ink or in the color of the most prominent type appearing on either the container or the package, that is, in such a fashion that the prominence and meaning of the warning is not obscured. Appropriate use of printing techniques, styles, colors and illustration should be utilized to aid the consumer in encountering and understanding the important meaning of the labeling. Warning or caution statements should be typeset in no less than eight-point type, or one-third the point size of the largest type face appearing on both the container and labeling, whichever is larger.

The Panel concludes that it is irrational and unsafe to recommend that any anorectal preparation be used "as needed" or "by continual application" or "for prolonged use" because this philosophy would promote unrestricted use beyond safe limits for OTC anorectal products. Because these ingredients are to be used on a short-term basis only, i.e., for not more than 7 days without improvement, the Panel considers these directions inappropriate and contrary to the concept of safe and effective ingredients for temporary relief of anorectal symptoms. If symptoms continue to occur or increase, the consumer should consult a physician to avoid any delay in establishing an accurate diagnosis and to begin necessary treatment of any serious disease condition. Furthermore, the continued use of certain ingredients may be harmful by producing an allergic reaction or skin irritation. (See part II. paragraph J. above—Allergy and Sensitization of the Anorectal Area.) Repeated use of anorectal products, while temporarily relieving symptoms, may mask more serious signs and symptoms.

In light of the above discussion regarding continued use, the Panel concludes that the use of anorectal products for more than 7 days is not recommended except under medical supervision and that the following warnings must appear in all labeling of anoretcal products under the heading "Warnings": (1) "If symptons do not improve, do not use this product for more than 7 days and consult a

physician." (2) "Do not exceed the recommended daily dosage except under the advice and supervision of a physician." (3) "If itching persists for more than 7 days, consult a physician." (See part II. paragraph E.1. above—Itching.)

The Panel emphasizes that OTC products are not appropriate for alleviating bleeding that may occur in the anorectal area and strongly recommends the following warning: "In case of bleeding, consult a physician promptly."

The Panel also recommends the following specific labeling be applied to the various anorectal dosage forms when indicated as external and/or intrarectal products under the heading "Warnings":

a. *External use*—(1) *For products that are ointments, creams, jellies, foams, pads, or gels for external use only.* "Do not put this product into the rectum by using fingers or any mechanical device or applicator." (See part II. paragraph B. above—Anatomy of the Anorectal Area.)

b. *Intrarectal use*—(1) *For all anorectal products for intrarectal use by insertion into the rectum, except protectants.* "The safety of this product has not been established for use by pregnant women or by nursing mothers." (See part II. paragraph N. above—The Use of Anorectal Drugs During Pregnancy and by Nursing Mothers.)

(2) *For products that are to be used with special applicators such as pile pipes or other mechanical devices.* "Do not use this product if the introduction into the rectum causes additional pain. Consult a physician promptly." (See part II. paragraph I.2. above—Ointment, creams, gels, jellies, and pastes.)

c. *For all (see outlines) anorectal products that contain at least one Category I anorectal ingredient other than a Category I protectant or astringent active ingredient.* "Do not use this product in children under 12 years of age except under the advice and supervision of a physician." (See part II. paragraph O. above—Pediatric Dosage.).

6. *Drug interaction precautions.* The Panel concludes that it is important for consumers to be aware that certain types of products should not be used concurrently. In such cases, the labeling of anorectal products must contain an appropriate drug interaction precaution under the heading "Drug Interaction Precaution." This warning is not applicable to all anorectal products and is discussed and applied later in this document. (See part III. below—Local Anesthetics and part IV. below—Vasoconstrictors.)

7. *Category II labeling.* The Panel has reviewed the labeling of products and ingredients submitted to the Panel and has concluded that some words and phrases are inappropriate for the OTC marketplace and recommends the withdrawal of these words and phrases from OTC labeling. Of particular concern are labeling claims containing the words "palliative treatment," "for treatment of hemorrhoids," "eliminates," or "treatment." The use of these words only serve to confuse and mislead the consumer because the implication is a curative or definitive action. OTC products are primarily for the relief of symptoms and not the treatment of disease.

Many labeling claims contain words that are too general, unclear, or redundant, and may be misleading when used alone, such as "simple anorectal irritation," "anorectal disorders," "simple inflammatory rectal conditions," "removes common causes of local irritation," "simple," "common," "uncomplicated," "minor," "superficial," "for hemorrhoids," "reliences painful distress," "alleviates irritation of mucous membrances," "use as a hygienic aide to remove the common causes of local irritation," "relieves," "soothes," "cools," "cooling," "minor rectal inflammation and irritation," "simple inflammatory rectal conditions," "in most cases," "concealed hemorrhoidal tissue," and "uncomplicated hemorrhoids."

The Panel is also concerned with the use of words or phrases describing anorectal conditions that are not easily disgnosed by the consumer and therefore are not appropriate for the OTC market, such as "anal eczema" and "psoriasis." Furthermore, the Panel is aware of current labeling that instructs the consumer to use the product "before or after hemorrhoidectomy," "for anorectal surgical wounds," "episiotomies," or ". . . sclerosing therapy." The Panel concludes that such labeling is not appropriate for consumers because these conditions are best treated under the advice and supervision of an attending physician.

The Panel has concluded that the use of certain protectant ingredients can provide lubrication in the anorectal area in the sense of making the area less dry and more pliable. (See part V. below—Protectants.) However, the Panel is aware of current labeling that is misleading because of reference to lubrication in the sense of laxation. The amount of lubricant used in anorectal preparations is not sufficient for laxation. The Panel, therefore, concludes that any wording or phrase that implies laxation, such as "provides lubrication and thus facilitates bowel movements," is clearly inappropriate.

Several products currently on the OTC market make claims of healing. The Panel concludes that such labeling as "natural healing is encouraged" implies a definitive therapeutic action not appropriate for OTC use as well as an implication that other products are synthetic or unnatural.

There are additional labeling claims currently used that state inaccurate or unproven facts. Because there are no sensory pain nerve fibers present in the rectal mucosa, words and phrases such as "temporarily relieves rectal itching" and "temporarily relieves rectal irritation" are clearly inappropriate as there is no feeling of pain or itch in the rectum.

Some labeling may cause the consumer to believe that certain products are superior to other available products for any of a number of reasons, for example: "contains no narcotic, anesthetic or habit forming ingredients," "nonnarcotic," "without the use of narcotics," or "contains no stinging, smarting astringents." These claims clearly imply a stronger or more effective product and also imply greater safety. Furthermore, the labeling implies that other products are narcotics, anesthetics, or astringents and are harmful without any evidence that this is so.

Labeling such as "medicinal," "recommended by physicians," "recommended by doctors," or "doctor tested" is misleading because these terms suggest that other products are not medicine or that other products are of no value because physicians do not recommend the other products or that all physicians recommend these products. If a product has been studied by scientifically approved methods, such information is acceptable as a basis for claims in labeling.

Claims as to length of effectiveness have not been proven and such claims as "sustained," "prolonged," or "effective over a long period of time" are not appropriate.

Claims such as "helps prevent scratching," "quiets the urge to scratch," and "checks scratching" are unproven and, furthermore, it is highly unlikely that prevention of scratching is possible. The desire to scratch occurs in some consumers whether or not itching is present. None of the data submitted refer to scratching as a symptom.

A claim such as "avoids embarrassment" is esthetic rather than a rational drug claim and is not appropriate for the OTC market.

Claims such as "torment" or "relieves the torment of . . ." are strong implications of extreme discomfort and the use of such claims is both excessive and misleading.

Claims such as "deeply penetrates mucous membranes," "penetrates denuded skin surfaces," and "reduces swelling of the mucosa and skin thus permitting a deep penetration of other ingredients" are not accurate. These statements have not yet been proven in the data submitted and are misleading because they imply a deep-seated source of discomfort.

8. *Category III labeling.* The Panel concludes that many labeling claims currently being made for OTC anorectal products have not been fully substantiated by the data presented to the Panel. However, the Panel is of the opinion that further testing is necessary to prove the appropriateness of these claims for Category I status.

The Panel classifies the following claims as Category III:

(1) "Holds the active ingredients in close contact with the irritated skin, thereby prolonging the beneficial action."

(2) "Prompt," "promptly," "fast," "quick," "quickly," "in minutes," and "rapidly" are Category III claims that can move to Category I if an ingredient can be shown to act within 20 minutes after application.

(3) "Prompt relief obtained for (specific number of hours) from pain and itching" and "promptly relieves pain and itching for (specific number of hours)," can be Category I claims if an ingredient can be shown to act within 20 minutes after application and the relief lasts as long as specified.

R. Pharmacologic Classifications of Anorectal Ingredients

Not all anorectal ingredients and products are used for the same indication; therefore, the requirements for effectiveness should not be the same. In an attempt to classify anorectal active ingredients used in the products submitted, it was necessary to distinguish between the pharmacologic activities and the resulting effectiveness for the claims of these products.

The Panel reviewed all anorectal active ingredients submitted to the Panel. The following pharmacologic classification of anorectal ingredients was developed by the Panel in an attempt to simplify categorization of ingredients and thereby eliminate labeling confusion: Local anesthetics, vasoconstrictors, protectants, counterirritants, astringents, wound-healing agents, antiseptics, keratolytics, anticholingerics, miscellaneous anorectal ingredients.

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S Summary Tables of Ingredient Classifications.

1. Category I (E--External Use and I--Intrarectal Use).

Local Anesthetics	Vasoconstrictors	Protectants	Counterirritants	Astringents	Keratolytics
Benzocaine in polyethylene glycol ointment (E).	Ephedrine sulfate in aqueous solution (E, I).	Aluminum hydroxide gel (E, I)	Menthol in aqueous solution (E)	Calamine (E,I)	Alcloxa (E)
					Resorcinol (E)
Pramoxine hydrochloride in a cream formulation (E).	Epinephrine hydrochloride in aqueous solution (E).	Calamine (E, I)		Witch hazel water (E)	
		Cocoa butter (E, I)		Zinc oxide (E,I)	
Pramoxine hydrochloride in a jelly formlation (E).	Phenylephrine hydrochloride in aqueous solution (E, I).	Cod liver oil (E,I)			
		Glycerin in aqueous solution (E).			
		Kaolin (E, I)			
		Lanolin (E, I)			
		Mineral oil (E, I)			
		Shark liver oil (E, I)			
		Starch (E, I)			
		White petrolatum (E, I)			
		Wool alcohols (E, I)			
		Zinc oxide (E, I)			

2. Category II (E--External Use and I--Intrarectal Use).

Local Anesthetics	Vasoconstrictors	Protectants	Counter-irritants	Astringents	Antiseptics	Keratolytics	Anticholinergic	Miscellaneous
Diperodon (E)	Epinephrine hydrochloride (I).	Bismuth subnitrate (E,I).	Camphor (E,I)	Tannic acid (E,I).	Boric acid (E,I).	Precipitated sulfur (I).	Atropine (E,I).	Collinsonia extract (E, I).
Phenacaine hydrochloride (E,I).	Epinephrine undecylenate (I).		Hydrastis (E,I).		Boroglycerin (E,I).	Resorcinol (I).	Belladonna extract (E,I).	E. coli vaccines (E,I).
			Menthol (I)		Hydrastis (E,I).	Sublimed sulfur (l).		Lappa extract (E,I)
			Turpentine oil, rectified (E,I).		Phenol (E,I).			Leptandra extract (E,I).
					Resorcinol (I)			Mullein (E,I).
					Sodium salicylic acid phenolate (E,I).			

3. Category III (E--External Use and I--Intrarectal Use).

Local Anesthetics	Vasoconstrictors	Protectants	Counter-irritants	Wound-healing agents	Antiseptics	Keratolytics
Benzocaine in polyethylene glycol ointment (I)	Epinephrine (E,I)	Bismuth oxide (E,I).	Juniper tar (E,I).	Cod liver oil (E,I)	Resorcinol (E)	Precipitated sulfur (E).
Benzyl alcohol (E,I).	Epinephrine undecylenate (E).	Bismuth subcarbonate (E,I).		Live yeast cell derivative (E,I).		Sublimed sulfur (E).
Dibucaine (E,I).	Phenylephrine hydrochloride suppositories (I).	Bismuth subgallate (E,I).		Peruvian balsam (E,I).		
Dibucaine hydrochloride (E,I).				Shark liver oil (E,I)		
Diperodon (I)				Vitamin A (E,I).		
Dyclonine hydrochloride (E,I).				Vitamin D (E,I).		
Lidocaine (E,I).						
Pramoxine hydrochloride in a cream formulation (I).						
Pramoxine hydrochloride in a jelly formulation (I).						
Tetracaine (E,I)						
Tetracaine hydrochloride (E,I).						

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III. Local Anesthetics

A. *General Discussion*

The Panel defines local anesthetics as agents that produce local disappearance of pain, burning, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations. Any ingredient claimed to be a local anesthetic must act by this mechanism. Theoretically, these effects could be manifested either on perianal skin or mucous membrane.

Local anesthetics, sometimes called topical anesthetics, share several general characteristics: (1) They are capable of acting on all conductive cellular membranes, including nerve tissue, cardiac, smooth, and skeletal muscle to alter conduction of electrical impulses and thus alter function of these tissues; (2) their structure is almost invariably composed of a lipid or fat-soluble portion connected by an intermediate molecular chain of specific lengths to a water-soluble component, usually a secondary or tertiary amine that can exist as a salt or base; (3) they can produce allergic reactions (Refs. 1, 2, and 3).

As anorectal ingredients, local anesthetics are applied both to rectal mucous membranes overlying large veins and to intact and/or abraded skin. The drugs have very different effects on these sites, and these effects are discussed below. Therefore, the Panel has classified ingredients for use at both sites.

1. *Intrarectal use.* The Panel concludes that there is insufficient evidence to prove safety or effectiveness of the local anesthetics used intrarectally (internally) in OTC anorectal products. Local anesthetics can easily diffuse through mucous membranes and, when applied intrarectally, can be absorbed directly into the systemic central and portal blood circulations (Refs. 4 and 5). Under certain conditions this absorption will be almost as rapid as intravenous administration (Refs. 6 and 7). Demonstration of the systemic absorption of an intrarectally administered local anesthetic in an anorectal preparation was presented to the Panel (Ref. 8). Both local and systemic absorption are concommitantly affected by conditions such as pH and formulation (Refs. 9 and 10). (See part II. paragraph G. above—Bioavailability of Anorectal Dosage Forms.) The achievement of a local effect tends to correlate with local absorption if sensory nerves are present; systemic effects also correlate with absorption (Ref. 11). Therefore, those local anesthetics that are the most effective are also the most toxic. Some local anesthetics are potentially toxic when applied to mucous membranes; they are absorbed systemically and in rare cases have caused death (Refs. 4 and 12).

The intrarectal effectiveness of all local anesthetics remains unsubstantiated and requires further testing. The Panel has carefully reviewed all available literature pertaining to this matter and has requested the opinion of several consultants (Refs. 13, 14, and 15). Although a wide variety of products are currently used intrarectally, several factors raise questions as to the therapeutic rationale for this route of administration (Refs. 16 and 17). There are no known sensory pain fibers above the anorectal (dentate) line (i.e., in the rectum). Clinically, one can demonstrate this by the fact that rectal mucosa can be damaged by electric cautery, biopsied, or incised with no pain. However, the sensation of pain in the rectum can be produced by bowel distention due to gas of feces. It has been argued that the mechanoreceptors associated with autonomic afferent fibers mediating this pain may be affected by intrarectal local anesthetics (Refs. 18, and 19 through 26). The use of a local anesthetic would be inappropriate because the signal indicating the need for evacuation would be lost if the local anesthetic were effective. Thus, the use of local anesthetics intrarectally raises a question because, theoretically, constipation might result from anesthesia of distention receptors in the rectal area and could also contribute to the increase of symptoms in the presence of anorectal disease (Refs. 19 through 26).

Another argument for effectiveness of intrarectal local anesthetics is that there is a deposit of local anesthetic along the external anorectal area in the course of introducing the product into the rectum (Ref. 27). This may occur, but the Panel concludes that the primary purpose of intrarectal local anesthetics is the relief of intrarectal symptoms.

A final argument is that medication placed in the rectum will seep out to affect the area below the anorectal line. Although seepage sometimes occurs in anorectal disease, the Panel concludes that this is a symptom that requires the attention of a physician and is not justification for using local anesthetics.

Two studies have been presented to the Panel which have examined the question of clinical pain relief with intrarectal use of two different local anesthetics. One well-designed, double-blind crossover study failed to demonstrate a significant difference between a placebo and a marketed ointment containing a local anesthetic (Ref. 28). Another study demonstrated no significant difference between control and local anesthetic products (Ref. 29). Therefore, the Panel concludes that the safety and the rationale for use, and thus the effectiveness of antrarectal local anesthetics in OTC anorectal products, remains to be established.

2. *External use.* Many local anesthetics have little effect on intact skin because of insignificant absorption. However, certain drugs that are alkaline in nature, poorly ionized, and lipophilic can penetrate the intact skin (Ref. 9). In addition, when the protective keratin layer of the skin is absent due to trauma or inflammation, local anesthetics in proper concentrations are effective on direct contact. Although local anesthetics can be absorbed to some extent, systemic absorption is not as rapid or as great from abraded skin as it is from mucous membranes. Therefore, the potential absorption from perianal skin does not constitute a significant hazard. Because the majority of anorectal disorders are associated with inflamed or denuded skin, the Panel concludes that, under the conditions set forth later in this document relating to concentration, pH, and formulation, certain OTC products containing local anesthetics are effective to relieve pain, itching and burning, irritation, and/or discomfort in this area. Ingredients approved for external use only should not be inserted into the rectum (intrarectally) by any device or in any dosage form.

Due to similarities in chemical structure, all of the local anesthetics are potentially capable of producing significant allergic reactions, both locally and systemically (Refs. 30, 31, and 32). A major consideration is that symptoms of allergy in the anorectal area such as itching and burning are indistinguishable from the same symptoms due to the anorectal disease. Accordingly, the Panel concludes that the labeling of anorectal products containing local anesthetics should bear the following warning about potential allergenicity, *"Caution:* Certain persons can develop allergic reactions to ingredients in this product. If the sympton being treated does not subside or redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician." (See part III. paragraph B.1. below—Category I Labeling.)

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3. *Minority report concerning the intrarectal use of local anesthetics.* The majority of the members of the Panel have concluded that local anesthetics used intrarectally are not proven effective at this time. It is believed that the majority based their conclusion on the fact that there are no anatomically identifiable sensory nerve endings or nerve fibers in the rectal mucosa or submucosa. Sensory nerve endings such as Ruffinian corpuscles, end bulbs of Krause, or Pacinian bodies are not reportedly identifiable in these outer layers of the rectum, above the anorectal line. However, there are known and identifiable nerve fibers and plexuses between the muscular layers that are associated with peristaltic muscular contraction of the rectum. These nerves are part of the autonomic nervous system and most are related to the pudendal plexus. Although the autonomic nervous system is primarily associated with motor function, the minority concludes that these nerve fibers, which are known to innervate the smooth musculature of the rectum, have synapses with cells in the myenteric and submucosal plexuses. In addition, the fibers have or are in adjacent association with sensory conducting nerve fibers, which transmit impulses to the central nervous system. Visceral afferent fibers from the rectum traverse the pelvic plexus and pass into visceral branches of the second, third, and fourth sacral nerves (Ref. 1).

The Panel heard statements and received reports from consultants regarding rectal innervation. The opinions varied and statements have been unspecific and, at times, have represented conflicting opinions regarding the alleged absence of sensation of the rectum.

The Panel recognizes that local anesthetics can be absorbed across the rectal mucosa and penetrate deep enough to enter the systemic circulation. It is acknowledged that the effects of mucous membrane absorption have been documented in statements by the majority regarding the ingredients reviewed. For example, Krantz and Carr (Ref. 2) state, "as a rule, the rectal dose of most drugs is about double the oral dose."

It is the minority opinion that there is definite sensation present in the rectum. It is true that certain superficial mucosal trauma such as rectal biopsy, fulguration, snaring, coagulation, etc., can occur without any associated sensation of discomfort due to pain. However, during instances when biopsy forceps is used which is not sufficiently sharp to effect a quick, clean cut, a pulling of tissue might occur which can be sensed as a significant discomfort. It is also known that there are definite sensory effects when the peritoneal or outer covering layer of an intestinal viscus is stimulated. Dilatation or distention of a hollow viscus such as the rectum produces significant clinical discomfort believed related to constriction of the involved blood vessels, which results in decreased tissue oxygenation (Ref. 3). Anorectal muscular spasm, involving skeletal and/or smooth muscle, can produce discomfort that might be associated with distention of the distal rectum.

The anatomic area above the anorectal line is a highly sensitive area. Any sensitive area requires the presence of physiologically functioning nerve receptors and fibers. This premise is documented by noting that when the rectum is filled with feces or gas, which raises the intraluminal pressure between 20 to 25 cm of mercury, the desire to empty the rectum is experienced. The receptors within the wall of the rectum are not only able to detect increases in pressure (pressoreceptors) but they can also differentiate whether the increase in pressure is due to feces, liquids, or gas (Ref. 4). The discriminating ability of these sensors is relied upon by individuals who risk flatulating in a public place.

The minority concludes that virtually any foreign body within the lumen of the rectum is definitely sensed by an individual who has an intact and nonpathologic nervous system. The mere introduction and insertion of a finger during a rectal examination commonly produces discomfort not only at the anal opening but also within the

luminal wall of the distal rectum. There is no question that such an examination probably also stimulates sensory nerve endings in the perianal skin. However, the distal portion of an inserted intraluminal object can also be sensed when it is in contact with the rectal mucosa. This, probably, is a result of distention pressure on surrounding tissue or deeper tissue layers that contain nerve fiber endings.

Many gastroenterologists, proctologists, and surgeons who perform sigmoidoscopic or colonoscopic examinations are well aware of the pain experienced during this examination in which there is direct contact between the sigmoidoscope and the rectal mucosa. Patients receiving this examination readily attest to the associated, significant rectal discomfort. This pain is sensed above the anorectal line and is associated with the movement of the distal end or tip of the instrument.

The minority concludes that degrees of anesthesia for significant relief of pain can be achieved with the intrarectal use of local anesthetics when anorectal conditions are associated with significant swelling and concomitant or resultant pressure acts to stimulate the sensory nerve fibers. Nerve plexuses in this area are associated with innumerable branching fibers. These nerves are in the ischiorectal area and probably have some branches to the rectum and other branches traversing inferiorly and supplying the perianal tissues below the anorectal line. Therefore, local anesthetics that may block the impulses of the nerve above the branching junction will afford relief of pain and discomfort to areas of the body inferior to the rectum and in the perianal area.

It is unfortunate that this Panel has been required to make conclusions regarding many of the ingredients associated with OTC hemorrhoidal drugs without appropriate clinical studies in the anorectal area. The minority concludes that the majority of the Panel's conclusions are based on the relatively small amount of poorly controlled published studies.

The marketing records or use experience of the various anorectal products containing local anesthetics for intrarectal use are significant. Advertising might be influential regarding the decision for the initial purchase of a product; however, the minority concludes that repeated sales of a product relate to clinical effectiveness. Consumers would not repurchase a product unless relief of symptoms had been achieved and, therefore, in most instances, ineffective products would not remain on the market.

In addition, the minority conclusion has been based greatly upon personal clinical experience with many patients who have attested to obtaining relief of discomfort associated with anorectal disorders with intrarectal use of local anesthetics.

In summary, the minority concludes that the intrarectal use of local anesthetics in OTC anorectal preparations is safe and effective in the dosages recommended in the ingredient statements within this document. This conclusion does not advocate or endorse the use of any specific product or ingredient.

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B. Categorization of Data

1. *Category I conditions under which local anesthetic ingredients are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I Active Ingredients

The Panel has classified the following local anesthetic active ingredients as generally recognized as safe and effective and not misbranded:

Benzocaine in polyethylene glycol ointment (external use)

Pramoxine hydrochloride in a cream formulation (external use)

Pramoxine hydrochloride in a jelly formulation (external use)

a. *Benzocaine in polyethylene glycol ointment (external use).* The Panel concludes that 5 to 20 percent benzocaine per dosage unit in polyethlyene glycol ointment is safe and effective for external use as a local anesthetic in OTC anorectal preparations up to six times daily and not to exceed 2.4 g per 24 hours. Products approved for external use only should not be inserted into the rectum by any device or in any dosage form. Only benzocaine base is discussed below; the salt form has been shown to be ineffective on intact skin and sunburned (abraded) skin (Ref. 1).

(1) *Description.* The local anesthetic benzocaine (ethyl aminobenzoate) is the ethyl ester of para-aminobenzoic acid. Due to its low solubility the base is poorly absorbed through intact skin; absorption through intact mucous membrane is minimal at recommended dosages (Refs. 1, 2, and 3).

(2) *Safety.* If benzocaine is absorbed systemically, reactions may include methemoglobinemia (Refs. 4 through 9). Three cases have been reported in the literature of systemic absorption in patients who developed methemoglobinemia within 3 hours of ingesting 162.5 to 325 milligrams (mg) benzocaine (Refs. 5 through 9). Nine cases of methemoglobinemia with blood levels in concentrations as high as 52 percent methemoglobin in infants treated with lotions, suppositories, or ointments containing benzocaine have also been reported (Refs. 8 and 9). However, Adriani and Campbell (Ref. 2) have used 20 percent benzocaine as a lubricant for intratracheal catheters nearly 10,000 times without untoward effects.

Furthermore, Adriani and Zepernick (Ref. 3) have reported only one case of methemoglobinemia developing in a patient 30 minutes after use of 20 percent benzocaine ointment on mucous surfaces for endoscopic examination in an estimated 144,000 cases seen over a 12-year period. The Panel, therefore, concludes that absorption leading to systemic effects is rare when applied topically and is not a significant consideration for external use.

The majority of unfavorable local reactions reported are of contact dermatitis or allergic sensitization (Refs. 10 through 15). These reactions are related to topical application of benzocaine. Abscesses and necrosis of skin with subsequent ulceration following treatment of pruritus ani with a 10 percent benzocaine product have been reported, but such reports are not applicable to the 7-day maximum use limit recommended in this document for all OTC anorectal products.

In summary, the Panel concludes that benzocaine is safe for external use in the doses described below, although it may cause adverse reactions in some cases, which will be indicated as labeling warnings.

(3) *Effectiveness.* Studies in guinea pigs, canines, and humans reveal that benzocaine is effective only in the base form. As a salt form, it is ineffective in an acid medium (pH 4 to 6) (Ref. 4). In a study of benzocaine base and salt along with 30 other local anesthetic-containing preparations, experimentally induced

itching, burning, and pain in suburned (abraded) skin were relieved by a 20 percent concentration of benzocaine base. The salt form and lower concentrations (below 5 percent) of the base were ineffective. In the same study, 10 to 15 minutes after application of the 20 percent benzocaine in polyethylene glycol ointment on normal skin, electrical stimulation produced no response (Ref. 1). Adriani and Zepernick (Ref. 3) have shown 20 percent benzocaine ointment to have a short onset (less than 30 seconds). Because duration of effect is directly related to duration of contact, effectiveness may be enhanced by slowing the rate of absorption when used in ointments (Refs. 17 and 18). Adriani and Zepernick (Ref. 3) have reported using benzocaine ointment (20 pecent benzocaine in polyethylene glycol ointment) for lubricating endotracheal catheters, oral and pharyngeal airways, and in laryngoscopic and bronchoscopic examinations in an estimated 144,000 cases with negligible side effects (except for one death which is considered to be an idiosyncratic reaction), and successful transient local anesthesia. The effectiveness of 20 percent benzocaine in polythylene glycol ointment applied externally in the anorectal area has been demonstrated in a study of 39 patients with painful hemorrhoids by Schmitz, Smith and Carberry (Ref. 19). The 20 percent preparation in polyethylene glycol ointment demonstrated relief in all patients compared to 15.4 percent and 38.4 percent failures for 1.0 and 0.5 percent benzocaine ointment, respectively (Ref. 19). Of those studies reporting effective use of benzocaine in anorectal disorders, the majority are anecdotal (Refs. 20, 21, and 22), but there are sufficient valid studies to establish effectiveness.

There is no significant difference in effectiveness between bonzocaine in polyethylene glycol ointment U.S.P. and benzocaine in polyethylene glycol ointment used in the above studies (Refs. 1 and 23). The Panel concludes, based on studies in the anorectal area and elsewhere, that 20 percent benzocaine in polyethylene glycol ointment is effective, but it is clear that certain other vehicles are not all equally effective in releasing benzocaine from the final formulation (Refs. 19, 23, and 24).

(4) *Dosage.* Adult external dosage is 5 to 20 percent benzocaine per dosage unit in polyethylene glycol ointment up to six times daily and not to exceed 2.4 g per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

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(b.) *Pramoxine hydrochloride in a cream formulation and pramoxine hydrochloride in a jelly formulation (external use).* The Panel concludes that 1 percent pramoxine hydrochloride per dosage unit in a cream or jelly formulation is safe and effective for external use as a local anesthetic in OTC anorectal preparations up to five times daily and not to exceed 100 mg per 24 hours. The pramoxine hydrochloride cream and pramoxine hydrochloride jelly referred to here are described in detail in a submission to the Panel (Ref. 1). Products approved for external use only should not be inserted into the rectum by any device or in any dosage form.

(1) *Description.* Pramoxine hydrochloride is chemically unrelated to the benzoate esters. It is an alkoxyaryl alkamine ether, with a change in the chemical configuration of the secondary amines (Ref. 2).

(2) *Safety.* Vairous animal studies have revealed few toxic effects except in large doses including 38 milliliters per kilogram (mL/kg) intravenously in the rabbit, and 460 mL/kg intraperitoneally in the mouse (Ref. 3). No toxic effects were noted in its clinical use as an aerosol foam (Ref. 4) or in suppositories and certain vehicles (Ref. 5) or in proctological procedures (Refs. 4 and 6). Two studies for potential irritation in humans failed to show evidence of reaction following continuous topical application of 1 percent pramoxine hydrochloride (Ref. 3). Although 1 percent of the patients did report transient burning sensation at the site of application in other clincial studies, 1 percent pramoxine hydrochloride used as a local anesthetic on mucous membranes of the tongue, urethral membrane, and the anorectal area was reported to cause no significant irritation (Ref. 4).

One report of toxicological studies of pramoxine hydrochloride in 10 guiena pigs revealed no sensitization; human sensitization testing using the Draize test revealed that the pramoxine hydrochloride was one-fifth as sensitizing as a comparable local anesthetic of unknown type (Ref. 3). Therefore, it can be concluded that pramoxine hydrochloride is capable of producing sensitization but is less likely to produce a reaction than other common local anesthetics because of its different chemical structure (Ref. 7).

In summary the Panel concludes that 1 percent pramoxine hydrochloride in a cream or jelly formulation is safe for external use (Ref. 1).

(3) *Effectiveness.* Anesthesia of mucous membranes of the palate, lip, and tongue has been demonstrated utilizing a 1 to 2 percent aqueous solution of pramoxine hydrochloride (Refs. 8 and 9), but such a formulation is not considered useful in anorectal products because the ingredient will not remain at site of action. Several clinical studies in the anorectal area using a pramoxine hydrochloride formulation indicate its effectiveness in producing local anesthesia as well as relieving symptoms (Refs. 4, 5, 6, and 10). In one uncontrolled study of posthemorrhoidectomy patients, 93 percent claimed good to excellent results (Ref. 4). In another uncontrolled study, all of 67 patients reported improvement. Of 27 patients with uncomplicated hemoorhoids, 18 were found to symptomatically improve sufficiently so as not to require surgery after use of a 1 percent concentration pramoxine hydrochloride formulation for 2 weeks. The remaining 9 of 27 also reported some symptomatic improvement. The remaining 40 patients with anorectal pain were also reported to consistently show symptomatic improvement (Ref. 6). In the same study six patients had a fissure or fistula; five of them could not undergo proctoscopy because of pain, but were able to receive proctoscopy after 1 week of treatment. The improved patients all experienced decreased pain (Ref. 6).

The Panel concludes that pramoxine hydrochloride in a cream or jelly formulation is effective as a local anesthetic in OTC anorectal preparations (Ref. 1).

(4) *Dosage.* Adult external dosage is 1 percent pramoxine hydrochloride per dosage unit in a cream or jelly formulation up to five times daily and not to exceed 100 mg per 24 hours.

(i) *For cream formulation.* Pramoxine hydrochloride 1 percent in a cream base containing methylparaben USP, propylparaben USP, cetyl alcohol NF, synthetic spermaceti NF, sodium lauryl sulfate USP, glycerin USP, and purified water USP.

(ii) *For jelly formulation.* Pramoxine hydrochloride 1 percent in a jelly base containing propylene glycol USP, hydroxypropyl methylcellulose USP (4000 centipoises), and purified water USP.

(5) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

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Category I Labeling

The Panel recommends the following Category I labeling for local anesthetic active ingredients to be generally recognized as safe and effective and not misbranded.

a. *Indications.* (1) "For the temporary relief of pain."

(2) "For the temporary relief of itching."

(3) "For the temporary relief of burning."

(4) "For the temporary relief of the discomforts of hemorrhoids (piles) or other anorectal disorders."

(5) "For the temporary relief of itching, burning and soreness of hemorrhoids or other anorectal disorders."

(6) "For the temporary relief of pain and itching of hemorrhoidal tissue or other anorectal disorders."

(7) "For the temporary relief of itching, burning and pain associated with hemorrhoids or other anorectal disorders."

(8) "For the temporary symptomatic relief of pain, itch, burning and soreness of some types of hemorrhoids or other anorectal disorders."

(9) "For the temporary relief of pain and itching due to painful hemorrhoids or other anorectal disorders."

(10) "For the temporary relief of pain and itching of hemorrhoids and other anorectal disorders."

(11) "Temporarily helps numb pain associated with hemorrhoids."

b. *Warnings.* (1) *"Caution:* Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician."

(2) *"Caution:* This product is for external use only. Do not apply inside the rectum in any way."

2. *Category II conditions under which local anesthetic ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredients

The Panel has classified the following local anesthetic active ingredients as not generally recognized as safe and effective or as misbranded:

Diperodon (external use)

Phenacaine hydrochloride (external and intrarectal use)

a. *Diperodon (external use).* The Panel concludes that diperodon is safe at the concentration used in OTC drug products but is not effective for external use as a local anesthetic.

(1) *Description.* Diperodon is a local anesthetic which is structurally different from many other common local anesthetics (Ref. 1). "Assuming that nupercaine is 20 times as active as cocaine, it is then about 8 times as active as diothane, although it is at least 20 times as toxic" (Ref. 2).

(2) *Safety.* There are little data on the safety of diperodon but its safety relates in part to the site of application and use in the marketplace with an approved new drug application since 1939 without significant hazard (Ref. 3).

There are not studies directly relating to the safe external use of diperodon. Although it may be absorbed through abraded skin, the Panel has considered this to be insignificant with regard to systemic toxicity due to the limited area involved.

Local irritation and allergic reaction are possible; however, in the limited reports available, local reactions have not been reported (Refs. 2, 4, and 5). It is likely, based on a longer duration of action, but not demonstrated, that diperodon can cause allergic reactions. Therefore, a general warning should be noted on the label. Diperodon-containing products were involved in only three incidents of accidental poisoning in 1973 and no reports in 1974, but no reactions were reported with them (Refs. 6 and 7).

(3) *Effectiveness.* Diperodon and oxyquinoline benzoate topical ointment was reviewed by the National Academy of Sciences, National Research Council (NAS/NRC) Drug Efficacy Study Group and was classified as possibly effective for the temporary relief of anorectal pain and itching and providing anesthetic and mild antiseptic action as published in the Federal Register of June 18, 1971 (36 FR 11756). The marketed product reviewed by the NAS/NRC group was the same product submitted to this Panel.

Diperodon has been used in a 0.5 to 1.0 percent concentration in clinical and experimental circumstances (Refs. 1, 8, and 9). In an effectiveness study, it was compared with benzocaine and lidocaine in eye abrasions and three types of burns on guinea pig skin (Ref. 1).

This study demonstrated variable effectiveness of all three agents depending on site of application and injury, although diperodon did appear to be effective (Ref. 1). An unpublished study showed significantly greater relief of moderate and severe but not mild post-hemorrhoidectomy pain with diperodon than the placebo at 40 and 60 minute intervals (Ref. 10). Other studies showed no statistically significant difference between diperodon and the placebo for pain, pruritus, or burning (Refs. 5 and 11 through 14). A double-blind controlled study showed a trend in favor of diperodon over the placebo but no significant differences (Ref. 15). The Panel concludes that, because of the studies cited above, the effectiveness of diperodon when used externally for anorectal use in concentrations of 0.5 to 1.0 percent has not been established.

(4) *Evaluation.* The studies cited utilize double-blind, controlled techniques in the anorectal area, and the predominant results show no statistical difference between diperodon and placebo. Therefore, it is the conclusion of the Panel that diperodon in anorectal OTC preparations is not effective for external use.

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b. *Phenacaine hydrochloride (external and intrarectal use).* The Panel concludes that phenacaine hydrochloride is not safe because it is readily absorbed and is toxic at the concentrations used in OTC anorectal products. The Panel further concludes that there is insufficient evidence to prove it is effective in anorectal products.

(1) *Description.* Phenacaine hydrochloride is a derivative of phenitidin and was one of the first local anesthetics to be used. Its development was based on the known antineuralgic effects of phenitidin (Ref. 1). It is relatively soluble in water, ethanol, and carbon tetrachloride, but not ether. It is not an ester and differs greatly in chemical structure from the majority of local anesthetics.

(2) *Safety.* Phenacaine hydrochloride is well-absorbed across the mucous membrane and is systemically toxic at specific concentrations (Ref. 2). Therefore, this agent cannot be considered as a safe local anesthetic for OTC use because the dose required to be effective would produce toxic systemic effects. Phenacaine hydrochloride is a more potent and more toxic local anesthetic than cocaine which has well-established toxicity and is effective when used in medical procedures (Ref. 3). No specific data exist related to the safety of phenacaine hydrochloride in anorectal preparations or in other uses requiring application to the mucous membranes. In the eye it has been used in a 1 percent concentration, but absorption is minimal or very small through the sclera, the cornea, and the conjunctiva. Therefore, in 1 percent concentration in the eye no toxic reaction has been recorded (Ref. 2).

Like other local anesthetics, toxicity is related to the effect on the central nervous system and in the heart muscle, including restlessness, tremor, clonic convulsions, and finally, respiratory depression. Phenacaine hydrochloride can also act on heart muscle to cause changes in excitability and conductivity (Ref. 1). In one commercial preparation (Ref. 4), a 20-mg dose per suppository is equal to 40 percent of the maximum allowable dose cited by Dreisbach (Ref. 5). A lower concentration of this agent might render it less hazardous, but because phenacaine hydrochloride has a very short duration of action, even in saturated solutions (Ref. 3), any advantage is reduced by virtue of the frequent applications that are then necessary and that might promote more frequent use, leading to a higher daily dose. At any site at which it is effective, it is also well-absorbed systemically and thus potentially toxic. Phenacaine hydrochloride cannot be considered safe for use in OTC anorectal preparations.

(3) *Effectiveness.* Although there are no available data regarding phenacaine hydrochloride as an anorectal agent, it is a moderately effective local anesthetic with a very short period of action (Ref. 3). One human study of phenacaine hydrochloride's effectiveness shows that 1 percent solutions were capable of eliminating a tingling sensation of the tip of the tongue for 3 minutes and saturated solutions of phenacaine hydrochloride eliminated the tingling sensation for 7.5 minutes (Ref. 3). The Panel concludes that

although phenacaine hydrochloride may be effective, it is unsafe for OTC use.

(4) *Evaluation.* Phenacaine hydrochloride is one of the more toxic of the local anesthetics at effective concentrations and has one of the shortest periods of effectiveness. Phenacaine hydrochloride has been almost completely replaced in the medical armamentarium by many other less toxic, longer acting, and safer local anesthetics. Therefore, it is the conclusion of this Panel that this ingredient cannot be considered safe and effective for OTC anorectal preparations.

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Category II Labeling

The Panel concludes certain labeling claims related to the safety and/or effectiveness of phenacaine hydrochloride are unsupported by scientific data and in some instances by sound theoretical reasoning: (See part II. paragraph Q.7. above—Category II Labeling.)

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredients

The Panel concludes that the available data are insufficient to permit final classification of the local anesthetic active ingredients listed below. The Panel believes it is reasonable to provide 2 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed in OTC products:

Benzocaine in polyethylene glycol ointment (intrarectal use)

Benzyl alcohol (external and intrarectal use)

Dibucaine (external and intrarectal use)

Dibucaine hydrochloride (external and intrarectal use)

Diperodon (intrarectal use)

Dyclonine hydrochloride (external and intrarectal use)

Lidocaine (external and intrarectal use)

Pramoxine hydrochloride in a cream formulation (intrarectal use)

Pramoxine hydrochloride in a jelly formulation (intrarectal use)

Tetracaine (external and intrarectal use)

Tetracaine hydrochloride (external and intrarectal use)

a. *Benzocaine in polyethylene glycol ointment (intrarectal use).* The Panel concludes that 5 to 20 percent benzocaine per dosage unit in polyethylene glycol ointment is safe for intrarectal use as a local anesthetic in OTC anorectal preparations but that there is insufficient evidence to prove effectiveness.

(1) *Description.* (See part III. paragraph B.1.a.(1) above—Description.)

(2) *Safety.* (See part III. paragraph B.1.a.(2) above—Safety.)

(3) *Effectiveness.* It is known that the anesthetic effect of benzocaine is related to its contact with a surface and that it is poorly soluble. Adriani et al. (Ref. 1) have reported using 20 percent benzocaine in polyethylene glycol ointment on mucous membranes for lubrication of endotracheal catheters, oral and pharyngeal airways, laryngoscopy and bronchoscopy in an estimated 144,000 cases with negligible side effects and successful transient local anesthesia. The use of benzocaine in these patients was to eliminate gag, cough, or laryngospasm reflexes and not primarily to relieve pain. Because there are no sensory pain nerve fiber endings in the mucosa of the gastrointestinal tract (Refs. 2 and 3), effectiveness is not altered by the fact that suppositories and ointment, once inserted, do not stay in the lower rectum but may drift up the rectum from 4 to 12 cm above the anal sphincter (Ref. 4). Relief of pain with benzocaine used intrarectally has not been established (Ref. 5). Thus, the Panel concludes that there are insufficient data to prove that benzocaine 5 to 20 percent concentration in polyethylene glycol ointment used intrarectally is effective in OTC anorectal products as a local anesthetic. (See part III. paragraph B.1.a.(3) above—Effectiveness.)

(4) *Proposed dosage.* Adult intrarectal dosage is 5 to 20 percent benzocaine per dosage unit in polyethylene glycol ointment up to six times daily and not to exceed 2.4 g per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* The Panel has placed 5 to 20 percent benzocaine in polyethylene glycol ointment for intrarectal use in Category III because effectiveness of its use in seriously questioned by anatomical and physiological knowledge indicating no rationale for effective relief of symptoms. However, the possibility exists that benzocaine and other local anesthetics may be effective in the anorectal area. Satisfactory proof of effectiveness would require controlled clinical studies utilizing benzocaine in polyethylene glycol ointment and placebo intrarectally as described elsewhere within this document. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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b. *Benzly alchol (external and intrarectal use).* The Panel concludes that 1 to 4 percent benzly alcohol per dosage unit is safe for external and intrarectal use as a local anesthetic in OTC anorectal preparations but that there is insufficient evidence to prove effectiveness.

(1) *Description* This is a simple organic compound found naturally in jasmine, hyacinth, and balsams of Peru and tolu. The synthetic form derived by hydrolysis of benzyl chloride from benzylaldehyde (Ref. 2). This drug is converted by the body to hippuric acid and excreted in the urine (Refs. 1, 3, 4, and 5).

(2) *Safety.* When injected, subcutaneously or intravenously, it can cause irritation and local neurolysis (Refs. 4 and 6). Injection into the blood stream can cause vasodilation; in concentrated solutions, it can cause central nervous system irritation with convulsions and subsequent paralysis of respiratory centers (Refs. 3 and 4). Excessive and repeated contact with the

skin can lead to dermatitis by dehydration and removal of the skin's protective layer of lipids (Ref. 6).

Used in concentrations of 1 to 4 percent, this compound is considered to be of low or slight toxicity. As this compound is used in solutions of 1 to 4 percent and in ointments up to 10 percent, its toxicity at this concentration is slight and/or low because it is not absorbed through the skin or mucous membranes (Refs. 1 and 7). Direct absorption into the blood stream is possible but unlikely, which may be an important factor when used on mucous membranes (Ref. 5).

In summary, the Panel concludes that benzyl alcohol is safe for external and intrarectal use because of poor absorption through skin in the doses described below, although it may cause adverse reactions in some cases which will be indicated as labeling warnings.

(3) *Effectiveness (external use).* Used as a local anesthetic on intact skin it is of little potency. One clinical study claims onset of action in 5 to 7 minutes and duration up to 4.6 hours (Ref. 8). Yet other partially controlled and uncontrolled studies indicate maximum effect for a brief time (Refs. 1 and 3). Claims of long duration of effect are not supported, but relief of itching for short periods of time is suggested by the literature (Refs. 1 and 3). One study showed no penetration through intact skin by 4 percent concentration even when combined with 2 percent benzocaine (Ref. 9).

The Panel concludes that there are insufficient data to conclude that benzyl alcohol used externally is effective in treating the symptoms of anorectal disorders. The compound is only weakly active, and its duration of activity is too short to offer substantial relief.

(4) *Effectiveness (intrarectal use).* Benzyl alcohol is relatively low in potency as compared with other local anesthetics (Ref. 10). On mucous membranes, it is slightly more effective than on intact skin (Refs. 4 and 11). But, even on mucous membranes, duration of effect in controlled studies is one-half hour (Refs. 1 and 3). In addition, benzyl alcohol acts to relieve itching (Refs. 1, 2, and 3). Because rectal mucosa does not itch and, in fact, does not have cutaneous nerve endings (Ref. 12), the validity of using this substance for intrarectal use is questionable. Thus, the Panel concludes that there is insufficient evidence to prove that benzyl alcohol used intrarectally as a local anesthetic is effective in OTC anorectal preparations.

(5) *Proposed dosage.* Adult external and intrarectal dosage is 1 to 4 percent benzyl alcohol per dosage unit up to six times daily and not to exceed 480 mg per 24 hours.

(6) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(7) *Evaluation.* The Panel raises a question concerning the intrarectal effectiveness of benzyl alcohol on an area that does not have sensory nerve fiber endings. At best, this is a short acting, low potency local anesthetic. To prove that benzyl alcohol is effective externally and intrarectally, double-blind, controlled, clinical studies must show statistically significant improvement with benzyl alcohol in final formulation, specifying vehicle, as tested against control, by use of questionnaires. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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c. *Dibucaine and dibucaine hydrochloride (external and intrarectal use).* The Panel concludes that there are insufficient data to prove that 2.5 to 20 mg dibucaine or dibucaine hydrochloride per dosage unit are safe and effective for external or intrarectal use as a local anesthetic in OTC anorectal preparations.

(1) *Description.* Dibucaine is the amide of *N*-diethylethylene-diamine and 2-butoxy cinchoninic acid. The aromatic residue and the terminal diethylamino group are thus joined via an amide linkage, rather than an ester, as is procaine. As a base, dibucaine is slightly water soluble and moderately lipid soluble, but its commonly used salt, the hydrochloride, is soluble in both water and organic solvents (Ref. 1). For the purpose of this discussion, dibucaine and dibucaine hydrochloride are pharmacologically equivalent and will be discussed as dibucaine. These compounds have had wide use as both a spinal and topical anesthetic for many years. Dibucaine and dibucaine hydrochloride are the most potent, toxic, and longest acting of the injectable local anesthetics (Ref. 2).

(2) *Safety (external).* When used externally, dibucaine is likely to be absorbed when applied to abraded or broken skin because of its chemical and physical characteristics, but the extent to which this occurs has not been studied. However, the Panel has concluded that dibucaine used externally in the recommended doses below will not constitute a significant systemic absorption hazard because of the limited area of abraded perianal skin.

The primary safety concern with external use relates to allergic reactions. The anorectal area is covered with clothing and often macerated; it should theoretically be more prone to sensitization. These allergic symptoms can easily be confused with the same anorectal disease symptoms (Ref. 3). Several reports of clinical dermatitis due to dibucaine, some severe, are in the literature (Refs. 3 through 7), and the sensitizing ability of this compound is well-documented (Refs. 8 through 11).

In seven clinical studies reported in a submission to the Panel, approximately 489 patients used a product containing dibucaine for 2 to 28 days under some medical supervision (Ref. 12). There were reports by individuals of more discomfort, vaginal irritation, pruritus, and dizziness after use of a whole 15 g tube (150 mg dibucaine) as one application. Reactions were experienced by 6 of 489 patients for dibucaine as compared with 10 of 279 for control. This study indicates a low rate of adverse

reactions. However, in a recent survey of doctors on the use of a product containing dibucaine, 7.9 percent (435) of the physicians responding reported awareness of adverse reactions to dibucaine, including one report of anaphylaxis and 264 reports of local allergic reactions (4.8 percent) as well as reports of burning (31 reports), pruritis (30 reports), irritation (33 reports), and rash (40 reports) (Ref. 13). The group carrying out the study considered it to be a poorly designed survey. The Panel notes, however, that despite its anecdotal character, the survey would indicate that adverse reactions do occur with the commercial preparation, and published reports do not reflect these occurrences.

Finally, the manufacturer of one preparation has reported 57 cases of local reactions, 20 cases of local irritation, although this represents a very small percentage of reported reactions in comparison to units sold (Ref. 12).

In conclusion, the Panel recognizes the potential for dibucaine to cause local irritation and allergic reactions and the need to indicate this on labeling. However, the Panel also concludes that dibucaine is sufficiently safe for external use in the anorectal area at the recommended dosage.

(3) *Safety (intrarectal use).* The primary concern for safety with intrarectal use of dibucaine relates to the potential for systemic absorption because dibucaine has been shown, along with tetracaine, to have unique cytotoxic effects not seen at any dose with other local anesthetics (Ref. 14). The significance of this potential in the anorectal area has not been established. Local irritation may also need consideration.

Dibucaine appears to have a greater margin of safety than cocaine, which has well-known toxicity. One study compared corneal anesthetic potency to convulsive concentration and found that the ratio for dibucaine was 1:1,500,000 as opposed to 1:33,000 for cocaine (Ref. 15). Thus, dibucaine could be useful at low doses where it might be less toxic.

In comparative studies, dibucaine has been shown to be 15 to 20 times more potent than procaine (Refs. 2 and 15), and an aqueous solution is readily absorbed from mucous membranes and skin (Ref. 16) so that systemic toxicity is possible with the use of anorectal preparations (Ref. 16). The absolute toxic dose in man is not known, although a maximum safe dose of 25 mg has been cited, and recently confirmed by Dreisbach (Refs. 17 and 18). A reasonable estimate of the toxic dose could be made by comparative studies of several local anesthetics administered intravenously in both rabbits (Ref. 19) and humans (Ref. 20), and by recent studies in dogs, monkeys, and humans (Ref. 21).

In both rabbits and humans, the relative toxicity of procaine to tetracaine was found to be approximately 1:8, suggesting comparable models (Refs. 19 and 20). In the rabbit study, the toxicity ratio of tetracaine to dibucaine was 1:0.35. Thus, it could be estimated that each 0.044 mg of dibucaine is equivalent in toxicity to 1 mg procaine when given intravenously in rabbits. In the human study of intravenous tetracaine, approximately 2.5 mg/kg (0.125 mg/minute for 20 minutes) produced central nervous system and cardiac symptoms and/or seizures (Ref. 20). Although no data on intravenous dibucaine use in man were found, the similarity of toxicity ratios of tetracaine and procaine in rabbits and man (Refs. 19 and 20) suggest that toxicity ratios of dibucaine to tetracaine, as established in rabbits, could at least be approximately extrapolated to man. Therefore, a comparable toxic intravenous dose of dibucaine would be approximately 0.8 mg/kg or 56 mg total for a 70 kg person. In the rabbit study (Ref. 19), the lethal dose of tetracaine was 7.4 mg/kg, and for dibucaine 2.9 mg/kg. Further intravenous toxicity estimates are given in another study in which ataxia, muscle tremors, or death were noted in dogs at 3 mg/kg and in monkeys at 0.5 to 1 mg/kg after intravenous doses of dibucaine (Ref. 21). This would tend to corroborate the above estimates.

Finally, data was presented to the Panel relating to the intrarectal absorption of dibucaine (Ref. 21). These studies were carried out on very small numbers of dogs, monkeys, and normal human subjects and measured blood levels of dibucaine after intrarectal administration of a commercial product to all subjects and after intravenous administration in dogs and monkeys. These studies provided relatively consistent estimates of blood levels obtained after administration of the commercially formulated drug. However, the study designs were deficient. Doses were not always comparable between subjects. Position and bowel function of subjects were not controlled. No physiological monitoring of vital signs and electrocardiograms were carried out. The small number of subjects did not allow statistical analysis.

The studies revealed several noteworthy findings: (i) An aqueous solution of dibucaine given intravenously is clearly lethal at levels of 3 mg/kg in dogs and 1 mg/kg in monkeys; (ii) Commercial preparations of dibucaine given intrarectally under the conditions of the study provided measurable blood levels, although these levels were less than 20 percent and usually less than 10 percent of the measured lethal or toxic intravenous doses; (iii) A relatively steady state blood level of dibucaine appears to be obtained within 24 to 48 hours of continuous rectal dosing of approximately three times daily, and there are measurable levels for 48 hours after the last dose.

The investigators concluded that the results suggest that intrarectal absorption of the commercial preparations of dibucaine does not give levels comparable to those seen after intravenous administration and that, because toxic effects were only seen after the higher blood levels were obtained with intravenous use, intrarectal use in man is safe (Ref. 21).

Although it is clear that under the conditions of the study rectal absorption of commercially formulated dibucaine did not give levels conparable to intravenous administration, the Panel has several objections to the study conclusion that intrarectal use of the commercial product is safe in man:(i) Absorption of the intrarectal dibucaine preparation was studied in normal subjects, and blood levels obtained varied two to sixfold in single and multiple doses. The blood levels at the maximum recommended dose of 300 mg daily were not studied (Ref. 22). Furthermore, the maximum safe dose was not established in these studies. In the presence of rectal pathology where the mucosal surface is inflamed or otherwise interrupted, absorption might well be greater and certainly more variable, and expected blood levels can not be estimated on the basis of the study presented (Ref. 21).

(ii) The safety of systemically administered dibucaine has not been studied in man or animals. A study has clearly shown that rectally administered dibucaine is absorbed systemically and has the potential of acting at other sites such as the heart and the central nervous system (Ref. 21). The potential for allergic reaction occurring is increased by the slow rate of elimination of dibucaine. No measures of cardiac or central nervous system function were made in this study, although they obviously would be required.

Reported toxicity causing four deaths in children after ingestion of dibucaine and in one infant after rectal application of an unknown amount of dibucaine, are

significant (Ref. 12); however, these appear to have been accidental overdoses. Nevertheless, these cases indicate potential toxicity from OTC dibucaine products.

No reports of fetal cardiac depression during pregnancy have been found due to dibucaine, but the ease with which this occurs with other local anesthetics (Refs. 23 through 27) would suggest that this is possible with dibucaine as well if it is systemically absorbed after intrarectal use. Limited absorption has been demonstrated and, therefore, suggests a potential safety problem during pregnancy (Ref. 21). The Panel concludes that the use of dibucaine in pregnancy is contraindicated and has recommended an appropriate warning.

Finally, the Panel concludes, on the basis of considerable data studied, that the safety of intrarectal dibucaine remains to be established because of its demonstrated systemic absorption.

(4) *Effectiveness (external use).* Effectiveness of dibucaine is altered by the vehicle and whether the dibucaine is present as the base or the hydrochloride. There were little data on external use. Dibucaine hydrochloride has been shown to be an effective anesthetic lasting 46 minutes after application of 2 to 4 mL of a 0.5 percent aqueous solution (10 to 20 mg) when applied to the tip of the tongue (mucous membrane) (Refs. 28 and 29), but it was not effective when applied to intact or sunburned skin (Ref. 30). Dibucaine base, combined with lanolin, petrolatum, and sodium bisulfite in a commercial preparation, was barely effective on sunburned skin (Ref. 30). In petrolatum, a 1 percent concentration of the base was effective on mucous membranes but not on the intact skin (Ref. 31). Although it is probable that both the base and hydrochloride are effective at low concentrations on mucous membranes and abraded skin, studies of other local anesthetics (Ref. 32) have shown that they are effective when the stratum corneum is interrupted (abraded skin). The conclusions on effectiveness are drawn from studies performed on final formulation (Ref. 30).

A significant proportion of anorectal conditions are characterized by abraded or macerated skin, but there are no studies using dibucaine in the perianal area. Therefore, the Panel has concluded that there are insufficient data to show that dibucaine is effective when used for these conditions.

(5) *Effectiveness (intrarectal use).* Dibucaine as the hydrochloride has been shown to be an effective anesthetic lasting up to 46 minutes after application of 2 to 4 mL of a 0.5 percent aqueous solution (10 to 20 mg) when applied to the tip of the tongue (Refs. 28 and 29). In petrolatum in a 1 percent concentration it was effective on all mucous membranes that are sensitive to pain, but not on intact skin (Ref. 31).

Although the base has been demonstrated to be more effective on skin than the salt, Adriani (Refs. 28, 29, and 33) postulates that this lack of effectiveness may relate to the formulation. It is probable that the hydrochloride is effective at low concentrations on mucous membranes. Thus, dibucaine is probably effective on the abraded or macerated skin of the anorectal area below the anorectal line. Its effectiveness with intrarectal use is less clear. Several clinical studies involving more than 600 patients have not clearly shown the effectiveness of this product for anorectal use (Ref. 34). Two other studies demonstrate that control preparations without dibucaine are quite as effective as the commercial dibucaine preparation (Refs. 35 and 36).

The Panel has considered at length the effectiveness of local anesthetics above the anorectal line (on muccous membrane) and has concluded that, because of the absence of pain sensation in this area, intrarectal local anesthetics are unproven. The results of the study of a dibucaine rectal preparation (Refs. 35 and 36) would tend to support the conclusion of the Panel.

(6) *Proposed dosage.* Adult external and intrarectal dosage is 2.5 to 20 mg per dosage unit up to three to four times daily and not to exceed 80 mg per 24 hours.

(7) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.) The following warning is recommended for dibucaine and dibucaine hydrochloride when labeled for intrarectal use: "Not for use in pregnant women because it may cause depression of fetal heart function."

(8) *Evaluation.* The Panel concludes that there is insufficient evidence at this time to recommend dibucaine or dibucaine hydrochloride as safe and effective for external or intrarectal use in OTC anorectal preparations and must be tested. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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(36) OTC Volume 120010, pp. 175–240.

d. *Diperodon (intrarectal use).* The Panel concludes that there are insufficient data to provide that 0.5 to 1.0 percent diperodon per dosage unit is safe and effective for intrarectal use as a local anesthetic in OTC anorectal preparations.

(1) *Description.* (See part III, paragraph B.2.a. (1) above—Description.)

(2) *Safety (intrarectal use).* The safety of diperodon for intrarectal use has not been established. As with most local anesthetics, it is likely to pass readily across mucous membranes and thus can be absorbed intrarectally. Toxic levels have not been established, although Dreisbach (Ref. 1) has defined 100 mg or 10 mL of a 1 percent solution of diperodon hydrocholoride as a safe does for topical use. Because it is reported to have a long duration of action, the potential for accumulation may be greater than other local anesthetics (Ref. 2). Diperodon has been shown to cause tissue damage when use for infiltration anesthesia after operations on the anus and rectum (Ref. 3). However, those clinical studies of its use in OTC anorectal drug products have not reported specific adverse effects (Refs. 4, 5, and 6).

(3) *Effectiveness (intrarectal use).* No published studies of the intrarectal use of diperodon have been found.

In an unpublished study with 54 patients with internal and external hemorrhoids, there was no statistically significant difference in effectiveness between drug and placebo for relief of pruritis, burning, or pain (Ref. 4). However, no distinction was made in the results between patients having internal and external hemorrhoids.

In an unpublished study of 50 patients, including patients with internal hemorrhoids, the results indicated only a trend in favor of the active ingredient (Ref. 5). Responses by patients having internal hemorrhoids and those patients using the drug intrarectally for other conditions were not analyzed separately. Therefore, no conclusion relative to intrarectal effectiveness can be reached on these data.

One additional unpublished study with 94 patients receiving an application of ointment on the morning of the first postoperative day resulted in no differences between the drug and the placebo (Ref. 6). The findings do not distinguish between intrarectal and external applications or effectiveness.

(4) *Proposed dosage.* Adult intrarectal dosage is 0.5 to 1.0 percent per dosage unit up to five times daily and not to exceed 100 mg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* The Panel concludes that there is insufficient evidence at this time to recommend diperodon as effective for intrarectal use in OTC anorectal preparations.

Double-blind, well-controlled clinical studies showing statistically significant improvement over control must be performed to prove that diperodon is effective intrarectaly. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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(5) OTC Volume 120075, Protocol 039–GA–005.

(6) OTC Volume 120075, Protocol 039–WS–003.

e. *Dyclonine hydrochloride (external and intrarectal use).* The Panel concludes that 0.5 to 1.0 percent dyclonine hydrochloride per dosage unit is safe for intrarectal use as a local anesthetic in OTC anorectal preparations but that there is insufficient evidence to prove effectiveness.

(1) *Description.* A propiophenone derivative, dyclonine is a local anesthetic base that forms salts with hydrochloric acid.

(2) *Safety (external use).* Clinical reports indicate a low incidence of reactions (Refs. 1, 2, and 3). For example, dyclonine in a 1 percent concentration in cream base was applied to 3,656 patients for topical anesthesia; only two cases of proven sensitivity were reported (Ref. 4). Further, 1 percent dyclonine has been used without reported toxic reactions prior to office cystoscopy in more than 1,500 patients (Ref. 1). There are isolated reports of both allergic reactions and cardiovascular collapse (Ref. 4).

In summary, the Panel concludes that dyclonine is safe for external use in the doses described below.

(3) *Safety (intrarectal use).* Toxic levels in humans from anorectal use have not been determined. In a study dealing with the safety of dyclonine hydrochloride following oral administration, 35 patients were given from 300 to 600 mg daily for periods of time varying from 1 to 12 weeks. No undesirable side effects occurred (Ref. 5). Convulsions and cardiovascular effects have been reported in animals by other workers with use of dyclonine (Ref. 4).

Dyclonine has been used effectively in a 1 percent concentration without toxic reactions prior to office cystoscopy in more than 1,500 patients (Ref. 1).

Although the intrarectal safety of dyclonine is unknown, the Panel concludes it to be safe at the recommended dosage in light of its apparent low toxicity at other sites.

(4) *Effectiveness (external use).* In an uncontrolled study, 1 percent dyclonine cream was used on 222 patients, 28 of whom had anogenital pruritus (Ref. 6). Seventeen of the 28 were reported to have "excellent" results in relieving their symptoms. In another uncontrolled study in 26 patients with pruritus ani,

good relief of symptoms was claimed in 19, while 7 of the 26 were considered treatment failures (Ref. 7).

However, in a double-blind study of 1 percent dyclonine cream in patients with various dermatoses, 48 of 58 patients were unable to differentiate between the active preparation and the placebo (Ref. 8).

Dyclonine in a 0.01 percent aqueous solution is effective on the rabbit cornea (Ref. 9) and when applied to the tip of the tongue in humans (Ref. 10).

In summary, dyclonine appears to be a local anesthetic that is active in aqueous solutions on the cornea. However, there are not sufficient clinical studies to substantiate its effectiveness in an anorectal preparation, so its effectiveness as an anorectal agent for external use remains to be established.

(5) *Effectiveness (intrarectal use).* No studies are available that relate to the intrarectal effectiveness of dyclonine. Dyclonine hydrochloride in concentrations of 0.5 to 1.0 percent has a rapid onset of action and a duration of effect comparable to that of procaine when used for topical anesthesia in otolaryngology (Ref. 11). It is absorbed through the skin and mucous membranes (Ref. 11). Although in aqueous solution it is known to be an effective topical anesthetic on mucous membranes (Refs. 8, 9, and 10), its effectiveness in the cream preparation is not well-established (Ref. 4). Further, in view of the absence of pain sensors in the rectum, the Panel has judged that the intrarectal effectiveness of dyclonine remains to be established.

(6) *Proposed dosage.* Adult external and intrarectal dosage is 0.5 to 1.0 percent per dosage unit up to five times daily and not to exceed 100 mg per 24 hours.

(7) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(8) *Evaluation.* The Panel does not have sufficient data at this time to recognize dyclonine hydrochloride as an effective local anesthetic for external or intrarectal use in the treatment of anorectal disorders. The Panel recommends further studies so that dyclonine hydrochloride could move from Category III to Category I. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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(8) OTC Volume 120029, Section V., Human Efficacy Data.

(9) Richards, A. B. et al., "General Pharmacology of 4-alkoxy-B-(1-piperidyl) Propiophenones," *Federation Proceedings,* 11:385, 1952.

(10) Adriani, J. et al., "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics,* 5:49–62, 1964.

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f. *Lidocaine (external and intrarectal use).* The Panel concludes that 2 to 5 percent lidocaine per dosage unit is safe for external use, but there is insufficient evidence to prove effectiveness as a local anesthetic in OTC anorectal preparations. Furthermore, there is insufficient evidence to prove safety and effectiveness for intrarectal use in OTC anorectal preparations.

(1) *Description.* Lidocaine is an aminoacylamide. It is a white to slightly yellow crystalline powder that is practically insoluble in water, but very soluble in alcohol and chloroform, freely soluble in ether, and dissolves in various oils and fatty type ointment bases (Refs. 1 and 2).

(2) *Safety (external use).* The Panel concludes that lidocaine is safe for external use in concentrations of 2 to 5 percent. Although lidocaine may be absorbed through abraded skin (Ref. 3), the Panel concludes this to be of insufficient concern due to the limited area involved, as well as the low systemic toxicity of lidocaine.

The local toxicity and allergenicity of lidocaine is lower than that of many local anesthetics, although the potential for allergic reaction does exist (Refs. 4, 5, and 6).

(3) *Safety (intrarectal use).* No information relating to the safety of intrarectal use of lidocaine was found in the literature. Lidocaine enjoys wide use for topical and injection anesthesia as well as intravenously for control of cardiac arrhythmias. When injected, it is considered more potent than procaine (Ref. 7). Chronic administration in controlled experiments in animals in doses far exceeding those in OTC drug products produced no adverse effects (Ref. 8).

The degree of rectal absorption of lidocaine remains unknown, although due to the ease of absorption of local anesthetics across mucous membranes, complete absorption must be presumed (Refs. 9, 10, and 11). However, because lidocaine is used intravenously on a routine basis and the kinetics are well-established (Refs. 12 and 13), the Panel concludes that the dosages proposed for anorectal products would not be a major safety problem.

(4) *Effectiveness (external use).* In concentrations of 2 to 5 pecent, lidocaine in a water-soluble vehicle has been considered effective when applied to mucous membranes and the broken skin (Refs. 1 and 14). Current evidence indicates that lidocaine is ineffective in concentrations of less than 6 percent on unbroken skin (Refs. 3 and 15). Because most anorectal disorders are characterized by abraded (broken) skin, lidocaine is expected to be effective in concentrations of 2 to 5 percent.

Double-blind studies evaluating the effectiveness of a lidocaine ointment versus a placebo in providing temporary relief of pain associated with acute anal fissure seem to indicate lidocaine ointment is effective (Ref. 8). The overall results, however, were inconclusive because both the 5 percent lidocaine ointment and the placebo demonstrated effectiveness, although that of the placebo ointment occurred at a lower level of probability. Further investigation using a larger number of cases of anal fissure than the number reported in the studies is indicated.

Recent data demonstrated the effectiveness of a 2.5 percent lidocaine ointment applied to the back or on the upper arm where the skin was abraded by a strip-tape method or by light curettage (Ref. 16). While the Panel recognizes the effectiveness of lidocaine on other skin sites, the Panel concludes that because of the uniqueness of the anorectal area, effectiveness must be demonstrated in the perianal area.

(5) *Effectiveness (intrarectal use).* The Panel questions the use of a local anesthetic in an area above the anorectal line, i.e., in the rectum where there are no sensory pain nerve fibers, and concludes that there is insufficient evidence at this time to recommend

lidocaine as effective for intrarectal use in OTC anorectal preparations.

(6) *Proposed dosage.* Adult external and intrarectal dosage is 40 to 100 mg per dosage unit up to five times daily and not to exceed 500 mg per 24 hours.

(7) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(8) *Evaluation.* Demonstration of effectiveness may be shown by observations of patients with excoriated skin in the perianal area, or the posthemorrhoidectomy, or postepisiotomy patient, or observations that depend upon artifically induced local abrasions. Demonstrating effectiveness by any one of these methods would satisfy the Panel's requirements regarding the effectiveness of lidocaine for external or intrarectal use in OTC anorectal preparations. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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(16) OTC Volume 120055.

g. *Pramoxine hydrochloride in a cream formulation and pramoxine hydrochloride in a jelly formulation (intrarectal use).* The Panel concludes that 1 percent pramoxine hydrochloride per dosage unit in a cream or jelly formulation is safe for intrarectal use as a local anesthetic in OTC anorectal preparations but there is insufficient evidence to prove effectiveness. The pramoxine hydrochloride cream and pramoxine hydrochloride jelly formulations referred to here are described in detail in a submission to the Panel (Ref. 1).

(1) *Description.* (See part III. paragraph B.1.b.(1) above—Description.)

(2) *Safety.* (See part III. paragraph B.1.b.(2) above—Safety.)

(3) *Effectiveness.* The Panel concludes that 1 percent pramoxine hydrochloride in a cream or jelly formulation (Ref. 1) when used intrarectally has not been shown to be effective as a local anesthetic in OTC anorectal preparations. The data reviewed by the Panel do not provide sufficient evidence of effectiveness (Refs. 2, 3, and 4).

(4) *Proposed dosage.* Adult intrarectal dosage is 1 percent pramoxine hydrochloride per dosage unit in a cream or jelly formulation up to five times daily and not to exceed 100 mg per 24 hours.

(i) *For cream formulation.* Pramoxine hydrochloride 1 percent in a cream base containing methylparaben USP, propylparaben USP, cetyl alcohol NF, synthetic spermaceti NF, sodium lauryl sulfate USP, glycerin USP, and purified water USP.

(ii) *For jelly formulation.* Pramoxine hydrochloride 1 percent in a jelly base containing propylene glycol USP, hydroxypropyl methylcellulose USP (4000 centipoises), and purified water USP.

(5) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* The Panel concludes that there is insufficient evidence at this time to recommend pramoxine hydrochloride in a cream or jelly formulation as effective for intrarectal use in OTC anorectal preparations (Refs. 1 through 4).

To prove that pramozine hydrochloride in a cream or jelly formulation is effective intrarectally, further testing is required. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III ingredients, Combinations, and Labeling in Category I.)

References

(1) OTC Volume 120084.
(2) OTC Volume 120015.
(3) OTC Volume 120039.
(4) OTC Volume 120046.

h. *Tetracaine and tetracaine hydrochloride (external and intrarectal use).* The Panel concludes that 10 to 20 mg tetracaine or tetracaine hydrochloride per dosage unit are probably safe as a local anesthetic in OTC anorectal preparations, but there are insufficient data to prove effectiveness for external or intrarectal use.

(1) *Description.* Tetracaine is a derivative of *p*-aminobenzoic acid in which a butyl group has been substituted for one of the hydrogens of the *p*-amino group (Ref. 1).

(2) *Safety (external use).* Tetracaine is a highly active and toxic local anesthetic (Ref. 2). Although tetracaine potentially can be absorbed through abraded skin, the Panel concludes that sytemic toxicity is not a major concern provided no more than a daily maximum of 100 mg tetracaine is used.

Adriani (Ref. 3) states that allergic reactions are usually the result of repeated exposures or cross-sensitization to drugs of the same or similar classification. Skin sensitivity to tetracaine has been confirmed by patch tests in 24 patients treated topically from 1957 to 1966 (Refs. 4 and 5). Eczema was often severe and cross sensititity was noted on several occasions (Refs. 4 and 5). Many patients are sensitive to tetracaine (Ref. 6), and while sensitivity develops in some patients within 1 or 2 weeks, sensitivity did not occur in others for over a year (Ref. 6). Thus, prolonged use of tetracaine in any of its forms should be undertaken with caution (Refs. 7 through 10). In summary, the Panel concludes that tetracaine is safe for external use in the doses decribed below.

(3) *Safety (intrarectal use).* Absorption from mucous membranes is rapid and may simulate slow intravenous injection (Refs. 2, 3, and 11). Tetracaine has been investigated and it has been found that the LD_{50} (lethal dose for one-half of test animals exposed to a substance) of equally effective concentrations of tetracaine in dogs was

similar to that of intratracheal instillation. Tetracaine is a highly active, highly toxic local anesthetic, about 10 times more toxic than procaine but more active, and can be employed in high dilutions (Ref. 2). Its ability to penetrate mucous membranes far exceeds procaine and approaches that of cocaine (Ref. 12). Tetracaine frequently shows cross-sensitivity reactions (Ref. 13).

Adriani and Campbell (Ref. 2) and Adriani (Ref. 3) have repeatedly emphasized the clinical hazards of cocaine and tetracaine to tracheal tissues. There are no known data on the use of tetracaine in the rectum. Based on absorption through other mucous membranes (Refs. 2, 3, and 11), it is probably absorbed from the rectal mucosa and thus into the systemic circulation. Therefore, the safety of tetracaine when used intrarectally remains to be established.

(4) *Effectiveness (external use).* Tetracaine hydrochloride is used to produce local anesthesia of the sclera, conjunctiva and mucous membranes (Ref. 3). Commercial products containing 0.5 to 2.0 percent tetracaine in ointment are used topically on minor burns and scalds, skin ulcers, and sunburn to relieve itching (Ref. 13) but have not been studied in the anorectal area. Clinicians have relied largely on subjective studies and clinical impressions rather than controlled studies in assessing the effectiveness of topical anesthetics. Using the Adriani technique (Refs. 14 and 15) of electrical stimulation to elicit cutaneous itch and pain without apparent injury to the skin, it was demonstrated that saturated solutions of tetracaine in water, 40 percent alcohol and 10 percent glycerin were effective on sunburned skin. None of the manufactured preparations tested completely blocked the sensation of itch and burning on intact skin stimulated electrically, with the exception of 20 percent benzocaine in polethylene glycol ointment (Refs. 14 and 15).

A 1 percent solution of tetracaine topically is as effective as a 10 percent solution of procaine when applied directly to a nerve trunk (Ref. 2). Stronger solutions have been used but no proof exits to show increased strength produces increased effects. Increased strength will produce increased toxicity. Therefore, the Panel concludes effectiveness has yet to be proven.

(5) *Effectiveness (intrarectal use).* No studies were found that relate to the intrarectal effectiveness of tetracaine. The effectiveness of tetracaine in this area, where no pain sensation is experienced, must be proven.

(6) *Proposed dosage.* Adult external and intrarectal dosage is 10 to 20 mg per dosage unit up to five times daily and not to exceed 100 mg per 24 hours.

(7) *Labeling.* The Panel recommends the Category I labeling for local anesthetic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(8) *Evaluation.* The Panel questions the use of a local anesthetic in an area above the anorectal line (in the rectum) where there are no pain sensory nerve fibers, and concludes that there is insufficient evidence at this time to recommend tetracaine as effective for intrarectal use in OTC anorectal preparations.

To prove that tetracaine is effective externally or intrarectally for use in OTC anorectal products, testing must be performed. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

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Category III Labeling

The Panel concludes that the available data are insufficient to permit final classification of the following claims.

Claims such as "prompt" and "quick acting" imply an activity that takes effect within 20 minutes; however, the data presented to the Panel are insufficient to substantiate a so-called "prompt" or "quick" action. Therefore, the Panel concludes that these claims as well as unspecified time claims such as "for hours" are indeterminate and not allowed until clinical study can correlate a specific time in minutes or hours for said claims. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

IV. Vasoconstrictors

A. General Discussion

The Panel defines a vasoconstrictor as an agent that causes temporary constriction of blood vessels. Although many substances constrict blood vessels, only those sympathetic vasoconstrictors used in OTC anorectal products were considered by the Panel. Sympathomimetic vasoconstrictors, hereafter referred to as vasoconstrictors, are chemical agents that are structurally related to the naturally occurring catecholamines, epinephrine, and norepinephrine (Ref. 1). These agents act as neural transmitters by carrying stimuli or messages from nerves to receptors in various parts of the body so that specific parts of the body will respond in some specific way (Ref. 2).

Vasoconstrictors attach to alpha and/or beta adrenergic receptors (Refs. 3 and 4). Alpha receptors are found in vascular beds, especially in arterioles (small arteries) and capillaries, where stimulation causes constriction. Beta receptors are found primarily in cardiac muscle where stimulation may cause increased force and rate of contraction of the heart (Refs. 1, 3 and 4). Beta receptors are also found in pulmonary muscles where stimulation causes relaxation of bronchial spasm (Refs. 1, 3 and 4). It is important to remember that a concomitant effect occurs on beta receptors in the heart and lungs when vasoconstrictors are applied to alpha receptors in the anorectal area.

The Panel has reviewed the available data and has included only three

vasoconstrictors within this document based on products submitted for review. Epinephrine stimulates both alpha and beta receptors. Ephedrine stimulates both alpha and beta receptors and, in addition, initiates the release of body stores of norepinephrine and indirectly produces an additional alpha receptor response. Phenylephrine has only alpha stimulating properties (Refs. 1 and 4). The response of blood vessels to epinephrine, ephedrine, and phenylephrine varies throughout the body, but the blood vessels to skin and mucous membranes are constricted by these drugs that act on their alpha receptors (Ref. 1). This vasoconstrictive effect on dilated skin vessels has been used in OTC products to treat congestion of nasal mucous membranes and has also been used to aid in control of minor bleeding (Refs. 1 and 5). However, the Panel concludes that claims for control of minor bleeding are not appropriate for OTC anorectal use and if bleeding occurs, a physician should be consulted.

Anorectal disorders include many ailments but hemorrhoids are now of the most common. Historically, hemorrhoids are believed to be an abnormal cluster of dilated veins, and the cause of hemorrhoids is believed to be venous stasis or blockage (Refs. 5 through 9). Recent studies indicate hemorrhoidal vessels may be arterio-venous anastomoses which are described as wide-bore connecting channels between the larger vessels (Refs. 9 and 10). Some investigators believe hemorrhoids resemble, anatomically, the corpus cavernosum of the penis and call the hemorrhoids corpus cavernosum recti (Refs. 8 and 11). Both corpuses can fill rapidly with blood and empty, but not with equal speed. Anatomical and radiological studies of injected specimens show similar structures called "bodies" (corpus) in normal patients as well as in those patients having hemorrhoids (Refs. 9 and 11). A new explanation for the cause of hemorrhoids is a downward slide of the anal canal lining which includes these "bodies" or arterio-venous anastomoses (Refs. 8 and 9). Oxygen content of blood from hemorrhoidal veins was studied by Thulesius and Gjores (Ref. 10) and was found to equal the oxygen content of central arteries and to far exceed the oxygen content of central and peripheral veins. The presence of this level of oxygen may explain the bright red or arterial type of bleeding described by patients and seen by surgeons. In this same study, blood flow measurements with a thermocouple in the anal canal demonstrated prompt response of mucosal perfusion by the topical application of vasoconstrictors which would be expected only if arterioles are present; venules do not respond to vasoconstrictors (Ref. 10).

Vasoconstrictors are reported to give relief of local itching by a minimal anesthetic effect (Ref. 12). This may be due to the same phenomenon; i.e., vasoconstriction of blood vessels of the skin, or it could be due to the chemical structure of vasoconstrictors which resembles that of local anesthetics (Refs. 1 and 4). The exact mechanism of this anesthetic effect is unknown, but the Panel recognizes the relief of itching by vasoconstrictors.

Because rectal absorption of an ingredient varies with the vehicle and pH of the rectum (Ref. 13), excessive or repeated dosing greater than 7 days may permit absorption of significant amounts of these agents into the bloodstream via the hemorrhoidal vessels, which can produce systemic effects.

Due to potential serious side effects of these agents and because useful effects are achieved with minimum quantities, the Panel has chosen to limit safe OTC dosages to safe intravenous dosages.

When used in recommended safe dosage for local effect, undesirable systemic effects can be avoided. These undesirable side effects can include elevation of blood pressure, cardiac arrhythmia or irregular heart rate, central nervous system disturbance or nervousness, tremor, sleeplessness, and aggravation of symptoms of hyperthyroidism (Refs. 1 and 4). Prolonged use of excessive dosage can lead to anxiety or paranoia (Ref. 4). More commonly, prolonged use of the correct dosage will lead to rebound vasodilatation and congestion, which is discussed in the findings of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products as published in the Federal Register of September 9, 1976 (41 FR 38396). This adverse effect on nasal mucous membranes is well-established, but there are no similar studies related to rectal mucous membrane, only the theoretical implications. Contact dermatitis following topical use of some vasoconstrictors has been reported (Ref. 14). Vasoconstrictors, if absorbed, can interact with monoamine oxidase inhibitors, which are used for mental depression (Refs. 1 and 4). The hypertensive effects of the vasoconstrictors may be potentiated by these psychotherapeutic agents and combined use can lead to serious, even lethal effects, such as a cerebral hemorrhage or a stroke (Refs. 1, 4, 15, and 16). Therefore, the Panel concludes that a caution as provided under labeling for products containing Category I vasoconstrictors is appropriate. (See part IV. paragraph B.1. below—Category I Labeling.)

The Panel concludes that sympathomimetic vasoconstrictors do cause constriction of the vascular bed in skin and mucous membrane in other parts of the body and can give a subsequent decongestive effect. The Panel recognizes partial relief of local itching is achieved by topical application of vasoconstrictors. The Panel recognizes that vasoconstrictors can be used for other reasons and that there are more effective agents for relief of local itching.

The Panel does not recognize or approve the use of vasoconstrictors for the control of minor bleeding. As bleeding may be a sign of conditions ranging from abrasions to cancer, the Panel concludes that conditions evidenced by bleeding should not be self-medicated and that the advice and supervision of a physician should be obtained. Therefore, the warning is warranted: "In case of bleeding, consult a physician promptly." (See part II. paragraph Q.5 above—Warnings.)

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B. Categorization of Data

1. *Category I conditions under which vasoconstrictor ingredients are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I Active Ingredients

The Panel has classified the following vasoconstrictor active ingredients as generally recognized as safe and effective and not misbranded:

Ephedrine sulfate in aqueous solution (external and intrarectal use) Epinephrine hydrochloride in aqueous solution (external use)

Phenylephrine hydrochloride in aqueous solution (external and intrarectal use)

a. *Ephedrine sulfate in aqueous solution (external and intrarectal use).* The Panel concluded that 2 to 25 mg ephedrine sulfate in aqueous solution per dosage unit is safe and effective for external and intrarectal use as a vasoconstrictor in OTC anorectal preparations up to four times daily and not to exceed 100 mg 24 hours.

(1) *Description.* Ephedrine sulfate, a fine white odorless crystal or power, is freely soluble in water and soluble in oil (Refs. 1 and 2). The aqueous solution is stable but is decomposed by exposure to light or heat. Solutions of 1 to 3 percent and 1 percent jelly are used as a nasal decongestant. Solutions of 3 to 5 percent have been used in the eye for mydriasis since 1895 (Ref. 3).

(2) *Safety.* Ephedrine sulfate is readily absorbed from the mucous membrane of the intestinal tract, including the rectum (Refs. 2, 3, and 4). In humans, this drug is excreted unchanged by the kidneys. Within 12 hours, 60 to 75 percent of the administered dose is excreted and approximately 100 percent is excreted in 24 hours (Ref. 3).

Drugs used in the anorectal area are in contact with normal and/or inflamed skin and rectal mucosa. Absorption depends on many factors. It varies from the same rate as intravenous injections to slower than oral absorption rates (Refs. 1 and 5) which require a larger quantity of drug to produce the desired effect. The Panel has chosen to equate safe OTC doses with safe intravenous doses because useful effects are obtained with a minimum quantity of drug. This approach provides a more desirable margin of safety if the consumer inadvertently or deliberately uses this ingredient in excess of the recommended dosage (Refs. 6, 7, and 8).

Published data on animals and humans relating to clinical reports of toxic reactions to ephedrine sulfate are discussed in the findings of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products as published in the Federal Register of September 9, 1976 (41 FR 38397). This data involves intravenous, intramuscular, and oral administration of ephedrine sulfate. There are significant undesirable effects with oral doses of ephedrine above 50 mg which include nervousness, insomnia, tremulousness, vertigo, headache, tachycardia, palpitation, and diaphoresis (Ref. 2). Otherwise safe doses of 15 to 50 mg may be dangerous if totally absorbed by patients who have hyperthyroidism, hypertension, or angina pectoris, or by patients taking digitalis for heart conditions (Refs. 2 and 9). Ephedrine has a more prolonged effect than epinephrine and both alpha and beta adrenergic effects. Chronic use of ephedrine may lead to anxiety and/or a paranoid state in adults (Ref. 6).

The hypertensive effects of ephedrine are potentiated by monoamine oxidase (MAO) inhibitors, as well as tricyclic antidepressants. Combined use can lead to serious, even lethal effects (Refs. 1 and 2). MAO inhibitors prolong sympathomimetic effect by delaying inactivation of the catecholamine norepinephrine. As a result, increased pressure develops in the blood vessels and cerebral (subarachnoid) hemorrhages or strokes have been reported with the use of MAO inhibitors and ephedrine sulfate at various dosage levels (Refs. 1 and 2). Contact dermatitis following topical use of ephedrine sulfate has been reported (Ref. 10). Also of importance is the fact that ephedrine sulfate antagonzies the tranquilizing effects of phenothiazines (Ref. 2). A warning about these agents is needed to alert persons against using this product without consulting a physician if they have heart trouble, thyroid disease, are taking digitalis or heart medicine, or are taking antidepressants or other psychotherapeutic drugs. With the above exceptions, available experimental data on the effect of ephedrine sulfate in animals and in humans indicate that it is safe for external use whether skin is abraded or intact when used in recommended dosages (Ref. 2). In persons free of the above diseases and not taking the above medications, ephedrine sulfate is considered a safe vasoconstrictor for internal and external anorectal application provided the dosage is limited to 2 to 3 sprays or drops of 0.5 to 1.0 percent, not more often that every 4 hours. Rebound congestion can occur with higher dosages (Refs. 2 and 7). This dosage is discussed in the September 9, 1976 document at page 38397.

(3) *Effectiveness.* With topical application of aqueous solution on nasal mucosa, the onset of action of ephedrine sulfate is from a few seconds to 1 minute, and the duration of its effectiveness may persist up to 2 to 3 hours as discussed in the September 9, 1976 document at page 38397. Vasoconstriction of capillaries and arterioles follows topical application of ephedrine sulfate to abraded skin as well as mucosa (Ref. 2 and 3). As a result, there is a decongestant effect and some reduction in swelling. Local relief of itching or minimal anesthetic properties are also reported (Refs. 4 and 11). Ephedrine has been used as an oral sympathomimetic and a topical nasal decongestant of low toxicity (Refs. 1, 2, 3, and 12). The therapeutic value of ephedrine sulfate is based on its ability to constrict arterioles, which is the mechanism by which it produces a decongestant effect. There has been no evidence to support vasoconstrictor effect on veins (Ref. 13). Ephedrine sulfate has been shown to be effective in the control of arteriolar bleeding (Ref. 2). Thulesius and Gjores (Ref. 14) have shown hemorrhoids to be a mixture of arterioles and venules (arterio-venous anastomoses) with blood oxygen content similar to central and peripheral arteries. Thus, this drug can constrict vessels and, therefore, decrease blood flow in the arterioles or capillaries and reduce the volume of blood delivered to the veins, although this effect has not been demonstrated on hemorrhoidal

vessels. Use of vasoconstrictors in the anorectal area has been found by thermocouple measurements to reduce blood flow (Ref. 14). If applied repetitively, ephedrine may lead to rebound congestion (Ref. 2). The Panel concludes that ephedrine is effective for the temporary relief of swelling in the anorectal area.

It appears reasonable that ephedrine sulfate in an ointment would provide better surface contact and greater effectiveness, but formulation sharply affects the ability of the active ingredient to be released to the skin or mucosa (Refs. 15 and 16). Neither a literature survey nor review of the submitted data provided effectiveness studies on a final formulation of ephedrine sulfate in an ointment.

The pharmcology of ephedrine is similar to epinephrine (Ref. 3). Topical application of epinephrine on intact skin to produce blanching will prevent pruritus due to histamine (Ref. 11). The chemical structure of vasoconstrictors is related to local anesthetics. Vasoconstrictors have been shown to exert some local anesthetic effect (Refs. 1, 2, and 11). Therefore, the Panel concludes that ephedrine sulfate in aqueous solution is effective as an antipruritic.

The effective dosage of ephedrine sulfate as a mucosal decongestant ranges from 0.5 to 1.0 percent (5 to 10 mg/mL in aqueous solution) or a maximum of 3 mg per dosage unit every 4 hours as also discussed in the September 9, 1976 document at page 38397.

(4) *Dosage.* Adult external and intrarectal dosage is 2 to 25 mg ephedrine sulfate in aqueous solution per dosage unit up to four times daily and not to exceed 100 mg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for vasoconstrictor active ingredients. (See part IV. paragraph B.1. below—Category I Labeling.)

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b. *Epinephrine hydrochloride in aqueous solution (external use).* The Panel concludes that 100 to 200 micrograms (μg) epinephrine hydrochloride in aqueous solution per dosage unit is safe and effective for use up to four times daily and not to exceed 800 μg per 24 hours.

(1) *Description.* Epinephrine is a short acting sympathomimetic agent. It is obtained either from the adrenal glands of animals or by chemical synthesis. It is a white powder, very slightly soluble in water and alcohol. It is insoluble in chloroform and ether. The levorotatory drug occurs naturally and is 15 times more active than the destrorotatory form. The racemic mixture has less activity, depending an the ration of levorotatory-to-dextrorotatory ephinephrine present. Epinephrine is assayed in terms of its content of the levorotatory form.

In solution epinephrine is readily oxidized and becomes inactive. Stability is enhanced in acid, but epinephrine deteriorates rapidly in alkaline solution (Refs. 1 and 2).

(2) *Safety.* In adults an increase in blood pressure follows the intramuscular injection of 1 to 5 μg (Ref. 3). The minimum lethal dose of epinephrine hydrochloride administered subcutaneously is presumed by Grollman and Grollman (Ref. 3) to be about 10,000 micrograms/kilogram (μg/kg) of body weight. The intravenous injection of as little as 300 μg has produced alarming symptoms in humans (Ref. 3). The chief hazards of intravenous injection above 500 μg are increased risk of stroke because of increased blood pressure, purmonary edema, and cardiac arrhythmias (Ref. 4). However, for acute asthma unresponsive to other drugs, large doses are tolerated, e.g., intravenous injection of 150 μg every 15 to 60 seconds has been used (Ref. 1). Because of similar chemical structure, undesirable effects of epinephrine hydrochloride described above are the same as for ephedrine sulfate. (See part IV. paragraph B.1.a. above—Ephedrine sulfate in aqueous solution (external and intrarectal use).)

Forsyth et al. (Ref. 5) have demonstrated with C-14 systemic absorption through mucous membrane of 23.8 to 91.5 percent (238 μg to 915 μg) of racemic epinephrine-C-14 hydrochloride in aqueous solution applied to fresh gingival lacerations in anesthetized Rhesus monkeys by means of gingival retraction strings. Concomitant elevation of systolic and diastolic pressures and of pulse rates from 4 to 18 percent were observed in their experiments. OTC preparations contain only a fraction (100 μg/g of ointment) of the epinephrine used in the Forsyth et al. study (Ref. 5), but these preparations do contain an amount similar to that used for the treatment of asthma.

When used externally in anorectal preparations such as an ointment, it would be highly unlikely that venous absorption would reach a toxic level, and any effect would be of short duration (Ref. 6). When epinephrine hydrochloride in aqueous solution is applied locally to intact skin, it usually produces such intense vasoconstriction that systemic absorption in prevented (Ref. 3). However, when a suppository or ointment is placed within the rectum that may be inflamed or have lesions on the mucosal lining, conceivably absorption of epinephrine could be rapid (Ref. 5) and if used alone could approach blood levels similar to those obtained with intravenous injections. Although there is some evidence that in

the presence of a bland vehicle absorption will be slowed, until proved otherwise, 100 percent absorption is assumed to provide an adequate safety margin in OTC products. (See part II. paragraph G. above—Bioavailability of Anorectal Dosage Forms.)

Because of these safety considerations, the Panel has set the upper limit of epinephrine hydrochloride in aqueous solution in OTC anorectal preparations for external and internal use at 200 μg per dosage unit.

(3) *Effectiveness.* The known therapeutic uses of epinephrine hydrochloride are to constrict arterial blood vessels of the skin, stimulate the heart, relax bronchioles, and induce glycogenolysis (Ref. 3). For anorectal disease, only vasoconstriction is of importance because of the resultant reduction of swelling that theoretically will follow a reduction in blood flow to the anorectal area (Ref. 7). Other effects can be to reduce pruritus and reduce swelling. When combined with local anesthetics for use by injections (Refs. 1 and 3), epinephrine hydrochloride in a concentration of 0.0005 percent (5 μg/mL) (Ref. 1) is generally sufficient to limit the absorption of local anesthetics, and this effect prolongs the effect of the anesthetics. Although a solution equivalent to 2 percent epinephrine base in a dosage form designed to deliver 1,000 μg/drop is used in the conjunctiva for glaucoma (Refs. 4 and 8), the concentration is rapidly reduced by lacrimal fluid and tearing. In the treatment of anorectal symptoms, epinephrine constricts arterioles, and the Panel concludes that this will decrease swelling of tissues; however, degradation of epinephrine due to the alkaline pH of the rectum is considered sufficient to reduce its effectiveness. The Ph of the rectum is 8 to 10 in some cases of pruritus and is rarely below 6 (Ref. 9). Epinephrine is extremely unstable and requires a buffered solution of pH 4.2 to remain stable (Ref. 10). It is possible that salts of epinephrine such as epinephrine undecylenate (Ref. 11) are effective, but there are no data to establish safety or effectiveness.

The Panel concludes that in the dosage recommended epinephrine hydrochloride in aqueous solution is safe for external and intrarectal use. It is effective for the temporary relief of itching and swelling when applied externally. Because it is inactivated by the alkaline secretions of the rectum, the Panel concludes that epinephrine hydrochloride is not active intrarectally. For the reduction of congestion and swelling, it has been used locally on the conjunctiva and to reduce nasal congestion (Ref. 1). However, in the latter case because of its secondary vasodilation effect, swelling may not respond or may even be greater than that initially observed (Ref. 1). Though it has been used in a 0.1 percent (1,000 μg/mL) solution for topical application and in suppositories (Ref. 1), the Panel did not receive any controlled studies indicating its value in OTC anorectal preparations and the recommendations are based on aqueous solutions used in the data.

Melton and Shelley (Ref. 12) found that the topical application of epinephrine hydrochloride in aqueous solution to the intact skin in sufficient quantity produced blanching and that it was impossible to produce pruritus in such an area by the subcutaneous injection of histamine. Histamine injected locally in normal skin routinely produced pruritus. These observations suggest that it is effective in the treatment of pruritus due to histamine release. Clinical studies have shown that it is effective to relieve certain itching dermatoses of the skin (Ref. 11). Epinephrine undecylenate ointment used in these studies was claimed effective to relieve itching only when the epidermis was abraded (Ref. 11). The safety and effectiveness of this form of epinephrine are discussed below. (See part IV. paragraph B.3.b. below—Epinephrine undecylenate (external use).)

The Panel concludes that epinephrine hydrochloride in aqueous solution having a concentration of 0.1 percent (1,000 μg/mL) is safe and effecive for temporary relief of itching and swelling of hemorrhoidal tissues.

Though local application is effective in providing vasoconstriction and cessation of bleeding that may result from irritation or excoriation, the Panel has concluded that no claims for control of bleeding can be made by OTC products.

(4) *Dosage.* Adult external dosage is 100 to 200 μg epinephrine hydrochloride in aqueous solution per dosage unit up to four times daily and not to exceed 800 μg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for vasoconstrictor active ingredients. (See part IV. paragraph B.1. below—Category I Labeling.)

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c. *Phenylephrine hydrochloride in aqueous solution (external and intrarectal use).* The Panel concludes that 0.5 mg phenylephrine hydrochloride in aqueous solution per dosage unit is safe and effective for use as a vasoconstrictor in OTC anorectal preparations for external and intrarectal use up to four times daily and not to exceed 2 mg per 24 hours.

(1) *Description.* Phenylephrine hydrochloride is structurally related to norepinephrine. it is a potent alpha adrenergic stimulant with little effect on the central nervous system. Phenylephrine, in contrast to epinephrine and ephedrine, reflexly slows the heart rate and increases the stroke output, but does not disturb cardiac rhythm. Its primary action is to produce vasoconstriction by a direct effect on receptors rather than by norepinephrine displacement. It is used parenterally, orally, and topically to produce generalized or nasal vasoconstriction (Refs. 1 and 2) and by injection to prolong the effects of local anesthetics (Ref. 3).

(2) *Safety.* The safety of phenylephrine hydrochloride decreases as the dose is increased, due to its ability to cause general arterial constriction and hypertension (Refs. 1 and 2). It is reportedly less likely to produce local irritation than other vasoconstrictors (Ref. 4). Systemic effects often increase in persons with

hyperthyroidism, hypertension, or cardiovascular disease, and in those persons who take certain antidepressant drugs such as monamine oxidase inhibitors and tricyclic antidepressants (Refs. 5 and 6). (See part IV. paragraph A. above—General discussion.) The amount of this drug absorbed from the rectal area is unknown, but the potential for complete systemic absorption through the hemorrhoidal veins would require that no more than the intravenous dose (0.5 mg) producing systemic effects (Ref. 2) be allowed for intrarectal application, despite the uncertainty of incomplete bioavailability from various vehicles. Accordingly, no more than 0.5 mg phenylephrine hydorchloride per application four times daily should be used (Ref. 2). As with any of the sympathomimetics described in this document, it should not be used in persons with the above described diseases or who are taking the above noted drugs.

(3) *Effectiveness.* Phenylephrine hydrochloride is a very efficient arteriolar constrictor (Refs. 1 and 2) and a nasal decongestant at 0.25 to 0.5 percent in aqueous solution, as described in the findings of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products as published in the Federal Register of September 9, 1976 (41 FR 38399). Studies of its effects on venous beds found the effects to be minimal (Refs. 1, 2, and 7), but no studies of its effects on the hemorrhoidal area were found. although some sources state that there is no evidence demonstrating the effectiveness of vasoconstrictors on hemorrhoidal veins (Refs. 7 and 8), the Panel concludes that phenylephrine hydrochloride has a beneficial effect on swollen hemorrhoidal tissue by virtue of reduction of capillary and arterio-venous congestion in the anorectal area (Refs. 9 and 10).

Phenylephrine hydorchloride is pharmacologically very similar to epinephrine. Temporary relief of itching produced by histamine has been secured after topical administration of epinephrine (Ref. 11). The Panel concludes that although no data are available, a similar effect may be claimed for phenylephrine.

In view of the unpredictable effects of final formulation on the ingredient, the effectiveness of phenylephrine hydrochloride in any final formulation other than an aqueous solution, such as suppositories, is discussed elsewhere in this document. (See part IV. paragraph B.3.c. below—Phenylephrine hydorchloride suppositories (intrarectal use) and part II. paragraph G. above—bioavailability of Anorectal dosage Forms.)

A 0.5 mg dose of phenylephrine hydrochloride in a 2 mL dosage unit is equal to the amount of phenylephrine used safely and effectively in producing nasal decongestion, as discussed in the September 9, 1976 document at page 38399. No other effective dose is known at this time; therefore, there is no basis for considering a dose other than 0.5 mg to be effective.

In summary, phenylephrine hydrochloride, in the recommended dosage, is safe and effective for external or intrarectal use for the temporary relief of swelling or itching in the anorectal area.

(4) *Dosage.* Adult external and intrarectal dosage is 0.5 mg phenylephrine hydrochloride in aqueous solution per dosage unit up to four times daily and not to exceed 2 mg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for vasoconstrictor active ingredients. (See part IV. paragraph B.1. below—Category I Labeling.)

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(10) OTC Volumes 120013 and 120014.

(11) Melton, F. M. and W. B. Shelley, "The Effect of Topical Antipruritic Therapy on Experimentally Induced Pruritis in Man," *The Journal of Investigative Dermatology,* 15:325–332, 1950.

Category I Labeling

The Panel recommends the following Category I labeling for vasoconstrictor active ingredients to be generally recognized as safe and effective and not misbranded.

a. *Indications.* (1) "Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders."

(2) "Temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders."

(3) "Temporarily shrinks hemorrhoidal tissue."

(4) "May temporarily relieve itching."

b. *Warning.* "Do not use this product if you have heart disease, high blood pressure, hyperthyriodism, diabetes, difficulty in urination, or are taking tranquilizers or nerve pills."

2. *Category II conditions under which vasoconstrictor ingredients or not generally recognized as safe and effective or are misbranded.* The Panel recommends that Category II conditions be eliminated from OTC anorectal products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredients

The Panel has classified the following vasoconstrictor active ingredients as not generally recognized as safe and effective or as misbranded:

Epinephrine hydrochloride (intrarectal use)
Epinephrine undecylenate (intrarectal use)
Epinephrine hydrochloride and epinephrine undecylenate (intrarectal use).

The Panel concludes that epinephrine hydrochloride and epinephrine undecylenate are safe but not effective intrarectally for use as a vasoconstrictor in OTC anorectal preparations.

(1) *Description.* (See part IV. paragraph B.1.b.(1) above—Description.)

(2) *Safety.* (See part IV. paragraph B.1.b.(2) above—Safety.)

(3) *Effectiveness.* The Panel concludes that intrarectal use of epinephrine hydrochloride and epinephrine undecylenate are not effective. Epinephrine is rapidly decomposed in alkaline solutions (Refs. 1 and 2). The pH of the rectum is normall greater than six (Ref. 3). Therefore, upon release of epinephrine from any final formulation, based on the data reviewed by the Panel, these ingredients are immediately rendered ineffective.

(4) *Evaluation.* The Panel concludes that the intrarectal use of epinephrine hydrochloride and epinephrine undecylenate are not effective at any

does submitted to the Panel, although they are safe at the dosage recommended for OTC anorectal products.

References

(1) "The United States Dispensatory and Physician's Pharmacology," 27th Ed., Edited by Osol, A. and R. Pratt, J. B. Lippincott Co., Philadelphia, PA, pp. 475–477, 1973.

(2) "The Merck Index," 8th Ed., Merck and Co., Inc., Rahway, NJ., p. 411, 1968.

(3) Granet, E., "Manual of Proctology," Year Book Publishers, Inc., Chicago, IL, pp. 258–261, 1954.

Category II Labeling.

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of vasoconstrictor drug products are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel considers the following claims to be misleading and unsupported by scientific data.

The claim that certain combinations of ingredients may be used to "shrink hemorrhoids" or to "shrink Hemorrhoidal tissue" has been made. The applicability of such a claim must rest primarily on a definition of the word "shrink."

According to Webster's dictionary, the word several meanings. There is general agreement that it refers to a reduction in size. However, opinions differ as to whether this signifies a temporary phenomenon or implies a permanent change.

The public is likely to consider that a permanent change is to be expected. However, data presented on vasoconstrictors indicate a temporary reduction in swelling but in the long run rebound swelling may occur. Therefore, to "shrink hemorrhoids" or "shrink hemorrhoidal tissue" is not achievable with OTC anorectal products and is misleading. The Panel concurs that vasoconstrictors can "temporarily reduce swelling" or "temporarily shrinks" and finds these words sufficiently strong to convey the usefulness of this class of ingredients in the short term treatment of anorectal symptoms. (See part IV. paragraph B.1. above—Category I Labeling.) Consumers with any persistent symptom should seek the advice of a physician.

The claim "control of minor bleeding" implies the ability on the part of the consumer to decide whether or not to seek medical attention based on knowing how to distinguish between blood originating from abrasions or irritations resulting from such activities as scratching or excessive rubbing with coarse toilet paper and blood originating from more serious lesions such as fissures and carcinoma. The quantity of bleeding cannot serve as an indicator of the seriousness of the condition, especially in the early stages of disease. Early detection of carcinoma is still the best available means of control, and this is best encouraged, in the opinion of the Panel, by directing the user of anorectal drug products to consult the physician if bleeding occurs for any reason. (See part II paragraph Q.5. above—Warnings.)

"Provides prompt and prolonged decongestion and vasoconstriction" implies complete and final relief and is considered misleading.

3. *Category III conditions for which the avaialable data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredients

The Panel concludes that the available data are insufficient to permit final classification of the vasoconstrictor active ingredients listed below. The Panel believes that it is reasonable to provide 2 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained with 2 years, however, the ingredients listed in this category should no longer be marketed in OTC products:

Epinephrine (external and intrarectal use)
Epinephrine undecylenate (external use)
Phenylephrine hydrochloride suppositories (intrarectal use)

a. *Epinephrine (external and intrarectal use).* The Panel concludes that there are insufficient data to establish the safety or effectiveness of epinephrine for external or intrarectal use as a vasoconstrictor in OTC anorectal preparations.

(1) *Description.* (See part IV. paragraph B.1.b. (1) above—Description.)

(2) *Safety.* The safe use of the epinephrine moiety is discussed in depth earlier in this document. (See part IV. paragraph B.1.b.(2) above—Safety.)

(3) *Effectiveness.* The effectiveness of epinephrine hydrochloride in aqueous solution has been established. (See part IV. paragraph B.1.b.(3) above—Effectivness.) Epinephrine in the base form is not soluble in water, and therefore, the Panel concludes that the effectiveness of epinephrine base has not been established.

(4) *Proposed dosage.* Adult external dosage is 100 to 200 μg per dosage unit up to four times daily and not to exceed 800 μg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for vasoconstrictor active ingredients. (See part IV. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* Data to demonstrate safety and effectiveness as an anorectal ingredient will be required in accordance with the guidelines set forth earlier in this document. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

b. *Epinephrine undecylenate (external use).* The Panel concludes that there are insufficient data to establish the safety or effectiveness of epinephrine undecylenate.

(1) *Description.* Epinephrine undecylenate is presumed to be a short acting sympathomimetic agent, chemically, an ester of epinephrine base (Ref. 1).

(2) *safety.* The safe use of the epinephrine moiety is discussed in depth earlier in this document. (See part IV. paragraph B.1.b.(2) above—Safety.) The safe use of epinephrine undecylenate remains to be established, although experimental evidence implies a degree of safe use (Ref. 1).

(3) *Effectiveness.* The effectiveness of the epinephrine moiety in a final formulation has been discussed in depth earlier in this document. (See part IV. paragraph B.1.b.(3) above—Effectiveness.) The Panel does not have sufficient data to establish effectiveness of epinephrine undecylenate, nor is there sufficient evidence that this ingredient in final formulation becomes available and effective at the site of action (Ref. 1). (See part II. paragraph G. above—Bioavailability of Anorectal Dosage Forms.)

(4) *Proposed dosage.* Adult external dosage is 100 to 200 μg per dosage unit up to four times daily and not to exceed 800 μg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for vasoconstrictor active ingredients. (See part IV. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* Data to demonstrate safety and effectiveness as an anorectal ingredient will be required in accordance with the guidelines set forth earlier in this document. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

Reference

(1) OTC Volume 120002, p. 47.

c. *Phenylephrine hydrochloride suppositories (intrarectal use).* The Panel concludes that phenylephrine hydrochloride is safe at the recommended dosage but there are insufficient data to establish effectiveness in the final formulation.

(1) *Description.* Phenylephrine hydrochloride is a potent alpha adrenergic stimulant. (See part IV. paragraph B.1.c.(1) above—Description.)

(2) Safety. (See part IV. paragraph B.1.c.(2) above—Safety.)

(3) *Effectiveness.* The effectiveness of phenylephrine hydrochloride as a vasoconstrictor in aqueous solution cannot be extrapolated to include effectiveness in final formulation as a suppository (Ref. 1) because there are insufficient data. (See part IV. paragraph B.1.c.(3) above—Effectiveness.)

(4) *Proposed dosage.* Adult intrarectal dosage is 0.5 mg per suppository up to four times daily, not to exceed 2 mg per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for vasoconstrictor active ingredients. (See part IV. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* The Panel concludes that pheynlephrine hydrochloride in a suppository dosage final formulation as submitted to the Panel is safe at the recommended dosage but must be evaluated for effectiveness in accordance with the guidelines set forth above for testing anorectal ingredients. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

Reference

(1) OTC Volume 120013 and 120014.

Category III Labeling

None.

V. Protectants

General Discussion

The Panel has defined protectants as agents that provide a physical barrier, forming a protective coating over skin or mucous membranes. Varying quantities of these agents are useful as pharmaceutical necessities, e.g., vehicles and stiffening agents, in the formulation of anorectal dosage forms, e.g., ointments, lotions, creams, suppositories, and dusting powders.

Protectants include absorbents, adsorbents, demulcents, and emollients.

Absorbents are agents that take up within themselves fluids or other substances on or secreted by the skin or mucous membranes. This definition could apply to materials such as cotton or toilet paper which absorb body tissue fluid and mucus, however, for purposes of this review, the definition applies only to ingredients submitted to the Panel for review.

Absorbents are agents that because of a fine state of subdivision, are capable of attaching to substances that are secreted by the skin or mucous membranes.

Demulcents are defined as agents that combine with water to form a physical relationship between molecules that are called colloidal solution; the cohesiveness of these solutions containing demulcents have the capacity to protect skin surfaces in a manner similar to that of mucus.

Emollients are defined as agents used to soften or protect internal or external body surfaces. They are substances derived from animal or vegetable fats or petroleum products. Some of the substances are water soluble and others are oil soluble (Ref. 1). By virtue of their physical nature, which allows homogeneous spreading over tissue surfaces, they can form a protective coat over affected areas, aid in softening dehydrated or injured areas by preventing tissue water loss (Refs. 2 and 3), and tend to counteract symptoms and signs of drying skin (Refs. 2 and 4). This group also includes some substances such as glycerin which bind water tightly, but also fit the definition of emollients (Ref. 1). In the therapy of anorectal problems, emollients should be avoided because they can produce blockage of hair follicles and gland ducts (Refs. 5, 6, and 7). Many agents with emollient effects are also used as vehicles, bases, or carriers for pharmacologically active agents, and the Panel recognizes the dual purpose of their use (Refs. 1 and 8).

As a general rule, protectants are not absorbed through intact or broken skin or mucous membranes. The majority of ingredients considered in this section are relatively inert and are safe regardless of the amount that is applied to the anorectal area. Absorption can occur with the bismuth compounds, so these ingredients may be unsafe and will be discussed later within this section. Allergic reactions may occur with certain ingredients such as wool alcohols, and these are also identified and discussed later.

In determining the effectiveness of these agents, the Panel has concluded that protectants, alone or in combination, are of therapeutic value by providing a physical barrier that prevents irritation of anorectal tissue. A second action of protectants is to prevent water loss from the stratum corneum of the skin.

The Panel believes that the concept of protectants providing a physical barrier over anorectal tissue and preventing further insult is reasonable and useful. The barrier effect of protectants is supported by data indicating that infant perianal skin is afforded significant protection against diaper wetness by application of a continuous film of petrolatum applied to the skin in the diaper area (Ref. 6).

The effectiveness of protectants in providing an occlusive film that prevents transepidermal water loss has been reported (Refs. 10 and 11). For example, data have been presented to the Panel (Ref. 12) indicating that the occlusive thickness needed to reduce water loss to zero ranged from a low of 0.26 mm for light mineral oil to a high of 0.96 mm for a cream consisting of only 24 percent protectants (or 33 percent total emollients and humectants). Thus, assuming an average dose of 2 g, when petrolatum (which has a specific gravity of 0.8) is applied topically over an area of 36 cm^2, which is approximately equal to the perianal skin surface, it would result in a film thickness of 0.65 mm. However, such a film will not stay in place if a protective ingredient is a liquid of very low viscosity or is a powder (Ref. 12). Furthermore, when applied to the anorectal area, a protectant is subject to removal by clothing, as well as during and after bowel movement. The importance of water in the outer layer (stratum corneum) of the skin has been well established (Ref. 7). Drying of the stratum corneum may be a cause of itching, pain, and/or burning (Ref. 1). It is the Panel's opinion that irritants, whether incurred by the use of toilet tissue or inadequate cleansing of fecal material, will also aggravate these symptoms.

The Panel further concludes that to justify a claim for protective effect, either of the following criteria must be met: (1) At least one protectant must be present in at least 50 percent (1 g) of a 2-g dosage unit, or (2) a combination of two but not more than four protectants must be present for a combined concentration of at least 50 percent (1 g) of a 2-g dosage unit. For those protectant ingredients limited to concentrations of less than 50 percent, they may be used only in combination with other protectants.

This conclusion was based on the Panel's determination of an adequate quantity of an ingredient that would serve as a protectant. Berube and Berdick (Ref. 11) have defined "use thickness" as a practical measure of protectant effect against transepidermal

water loss, as opposed to an earlier work (Ref. 10) that provided a basis for the occlusive thickness of an ingredient necessary to provide zero transepidermal water loss. A minimum of 50 percent (1 g) of a 2 g dosage unit would still permit the addition of other active ingredients as well as any inactive ingredients that may be necessary to formulate a pharmaceutically acceptable preparation. This quantity of petrolatum, for example, when spread uniformly on an area 36 cm^2 (an area 2⅓ inches by 2⅓ inches) provides a layer that is approximately 0.3 mm in thickness. This thickness is approximately twice the "use thickness" which Berube and Berdick (Ref. 11) had demonstrated would be necessary to reduce transepidermal water loss by 50 percent. It has been chosen also because of the tendency of protectants to be removed from the anorectal area and because an adequate "use thickness" relative to tissue moisture loss can be effective only as long as it is a contiguous layer (Ref. 11). One g is adequate to shield the area from further insult. Frequent applications, up to six daily, would compensate for the difficulty of the consumer in achieving uniform application as well as maintaining an occlusive layer of the protectant.

This approach provides a reasonable basis for establishing the minimum quantity of an ingredient that must be present for a product to qualify as a protectant. If it can be shown by the same method (Ref. 10) that an ingredient can achieve the same effect at a lower concentration and is also able to relieve anorectal symptoms as discussed under Testing Guidelines, an exception to the 50 percent requirement should be considered. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I). This qualification does not eliminate the possibility of combining as many as four protectants to fulfill the 50 percent requirement.

Itching is a symptom that may arise from many causes. (See part II. paragraph E.1. above—Itching.) It is commonly associated with abraded or irritated epithelium resulting from an underlying disease or from scratching. Normal skin is unlikely to be associated with itching; consequently, itching can be relieved if abraded or irritated skin can be returned to normal. Protection of the perianal area from air, feces, or other irritants will lead to a diminution of irritation and itching. The Panel concludes that Category I protectants can make claims for relief of itching.

The Panel is unaware of any clinical studies showing the relief of burning, pain, and/or itching in the anorectal area by protectants. However, clinical use of protectants for centuries testifies to their effectiveness. Thus, protectants are generally recognized as effective when they provide an occlusive barrier that protects the anorectal area from further insult. The prevention of water loss may be an important factor even though studies in the anorectal area have not been done.

The limitation of four protectant ingredients provides reasonable latitude in the formulation of combinations. The inclusion of more than four active ingredients from the protectant group would only serve to confuse the consumer by the inference that "more" is "better." The Panel concludes that in view of the generally, chemically inert nature of protectants, interaction is unlikely. There is no evidence that combinations of two, three, or four protectants are any better than one. However, protectant active ingredients may also serve as pharmaceutical aids. In recognition of this dual function, the Panel concludes that the maximum number of protectant active ingredients in a product would be limited to four, based on the data submitted to the Panel that four was the maximum number of protectants currently used in OTC anorectal products (Ref. 13).

References

(1) Barnett, G., "Emollient Creams and Lotions," *in* "Cosmetics: Science and Technology," Volume 1, Edited by Balsam, M. S. and E. Sagarin, John Wiley and Sons, Inc., New York, pp. 82–104, 1972.

(2) Blank, I. H., "Factors Which Influence the Water Content of the Stratum Corneum," *Journal of Investigative Dermatology,* 18:433–440, 1952.

(3) Fisher, L. B. and H. I. Maibach, "The Effect of Occlusive and Semipermeable Dressings on the Cell Kinetics of Normal and Wounded Human Epidermis," *in* "Epidermal Wound Healing," Edited by Maibach, H. I. and D. T. Rovee, Year Book Medical Publishers, Inc., Chicago, IL, p. 113, 1972.

(4) Idson, B., "Dry Skin and Emolliency," *Drug and Cosmetic Industry,* 110:28–29 and 108–110, 1972.

(5) Swinyard, E. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Absorbable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Antiseborrheics, Melanizing and Demelanizing Agents, Mucolytics and Certain Enzymes," *in* "The Pharmacological Basis of Therapeutics," 4th Ed., Edited by Goodman, L. S. and A. Gilman, The Macmillan Co., New York, p. 988, 1970.

(6) Swinyard, E. A. and S. C. Harvey, "Topical Drugs," *in* "Remington's Practice of Pharmacy," 14th Ed., Mack Publishing Co., Easton, PA, pp. 763–772, 1970.

(7) Grollman, A. and E. F. Grollman, "Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, PA, p. 701, 1970.

(8) Blank, I. H., "Action of Emollient Creams and Their Additives," *Journal of the American Medical Association,* 164:412–415, 1957.

(9) OTC Volume 120052.

(10) Berube, G. R., M. Messinger and M. Berdick, "Measurement in Vivo of Transepidermal Moisture Loss," *Journal of the Society of Cosmetic Chemists,* 22:361–368, 1971.

(11) Berube, G. R. and M. Berdick, "Transepidermal Water Loss. II. The Significance of the Use Thickness of Topical Substances," *Journal of the Society of Cosmetic Chemists,* 25:397–406, 1974.

(12) Minutes of the OTC Panel on Hemorrhoidal Drug Products, 27th meeting, April 29 and 30, 1977.

(13) OTC Volumes 120001 through 120084.

B. Categorization of Data

1. *Category I conditions under which protectant ingredients are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I Active Ingredients

The Panel has classified the following protectant active ingredients as generally recognized as safe and effective and not misbranded:

Aluminum hydroxide gel (external and intrarectal use)
Calamine (external and intrarectal use)
Cocoa butter (external and intrarectal use)
Cod liver oil (external and intrarectal use)
Glycerin in aqueous solution (external use)
Kaolin (external and intrarectal use)
Lanolin (external and intrarectal use)
Mineral oil (external and intrarectal use)
Shark liver oil (external and intrarectal use)
Starch (external and intrarectal use)
White petrolatum (external and intrarectal use)
Wool alcohols (external and intrarectal use)
Zinc oxide (external and intrarectal use)

a. *Aluminum hydroxide gel (external and intrarectal use).* The Panel concludes that aluminum hydroxide gel is safe and effective as a protectant (adsorbent) in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit when present as a single protectant and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description* This is a suspension of aluminum hydroxide and hydrated oxide containing the equivalent of 3.6 to 4.4 percent of aluminum oxide. The substance may be prepared by a number of methods by which gels with different

physical properties are made (Refs. 1 and 2).

(2) *Safety.* The safety of aluminum hydroxide when used as an oral antacid preparation has been established in the final order for antacid and antiflatulent products generally recognized as safe and effective and not misbranded, as published in the Federal Register of June 4, 1974 (39 FR 19874), and therefore, can be assumed to be safe for external or intrarectal use in anorectal products. No reports of toxicity in animals has been reported after oral administration, as discussed in the proposal establishing a monograph for OTC antacid products published in the Federal Register of April 5, 1973 (38 FR 8717). In humans, the only adverse effects after oral administration consist of the rare occurrence of intestinal obstruction from masses of the unabsorbed gel, sequestration of phosphate, and interference with absorption of tetracycline and possibly other drugs. Evidence concerning interference with absorption of such drugs as tetracycline and anticholinergics is conflicting as discussed in the April 5, 1973, proposal, and is if little importance insofar as anorectal products are concerned. The drug is poorly absorbed from the gastrointestinal tract when taken by mouth, and doses of 5 to 30 mL up to 12 times daily have been used in humans (Ref. 1). It may be assumed, therefore, that absorption through the anorectal area is of no consequence. Insofar as use in anorectal products is concerned, the Panel has found no evidence of toxicity in animals or humans. Aluminum hydroxide has been used for the treatment of peptic ulcer (Ref. 3). This fact, in conjunction with the established safety as an orally administered drug, leads to the conclusion that it is safe for external or intrarectal use in anorectal products.

(3) *Effectiveness.* Local application of aluminum hydroxide gel has been used for the relief of many skin disease, e.g., weeping eczematous lesions, impetigo, epidermophytosis, and tinea (Ref. 4). In general, response is best with moist lesions associated with itching or inflammation, in which the gel acts as an absorbent (Ref. 1). Aluminum hydroxide gel thickened by the addition of kaolin was found effective in providing relief in moist pruritus ani in 93 of 98 patients (Ref. 5); absorption and inactivation of proteolytic enzymes or other irritants in the anal discharge are postulated by the author as the reasons for improvement. Pruritus ani associated with dry skin was not helped by the gel and, therefore, labeling must specify its use in the anorectal area for moist conditions which produce burning, pain, or itch (Ref. 5). Aluminum hydroxide gel has also been used successfully for relief of itching, burning, and pain due to excoriated skin secondary to ileostomies and colostomies (Refs. 6 and 7). In these studies the gel was thickened with kaolin to produce a combination with better adhesion to the affected area. The affected area should be free of petrolatum or greasy ointments prior to application because these substances will interfere with proper adhesion. After oral administration of a kaolin-aluminum hydroxide gel mixture, the author of another study concluded that the mixture adsorbed fecal bacteria completely (Refs. 7 and 8). The Panel finds that aluminum hydroxide is effective for use either intrarectally or externally in anorectal preparations at the recommended dosages.

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the following specific labeling:

(i) *Indications.* (*a*) "For the temporary relief of itching associated with moist anorectal conditions."

(*b*) "Temporarily protects irritated areas from irritating materials."

(ii) *Warning:* "Remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area."

References

(1) "The United States Dispensatory," 27th Ed., Edited by Osol, A. and R. Pratt, J. B. Lippincott Co., Philadelphia, PA, pp. 50–51, 1973.

(2) "The Merck Index," 8th Ed., Merck and Co., Inc., Rahway, NJ, p. 44, 1968.

(3) Adams, W. L. et al., "Aluminum hydroxide as an Antacid in Peptic Ulcer," *American Journal of Digestive Diseases and Nutrition*, 3:112–120, 1936.

(4) OTC Volume 120006, p. 138.

(5) Friedman, M. H. F., B. F. Haskell and W. J. Snape, "Treatment of Pruritus Ani by Local Applications of Aluminum Hydroxide Gel," *The American Journal of Digestive Diseases*, 15:57–60, 1948.

(6) Friedman, M. H. F., "Aluminum Hydroxide Gel for Erosions in Patients with Bowel Fistulas," *Journal of the American Medical Association*, 131:520–522, 1946.

(7) Spiesman, M. G., "Colloidal-Kaolin and Aluminum-Hydroxide Gel (Kalum) in the Management of Lower-Bowel Conditions," *The Review of Gastroenterology*, 10:191–200, 1943.

(8) OTC Volume 120006, p. 162.

b. *Calamine (external and intrarectal use).* The Panel concludes that 5 to 25 percent calamine per dosage unit (based on the zinc oxide content of calamine) when used as a single protectant is safe and effective for external and intrarectal use as a protectant in OTC anorectal preparations and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Calamine is a pink mixture containing not less than 98 percent zinc oxide, which is white, and 0.5 percent ferrous oxide which is red (Ref. 1). Calamine is an odorless, fine powder that is insoluble in water and nearly completely soluble in mineral acids (Refs. 2, 3, and 4).

(2) *Safety.* The pharmacology of this substance is essentially the same as that of zinc oxide and the substance is, therefore, safe for anorectal use. (See part V. paragraph B.1.m.(2) below—Safety.) The ferrous oxide is a pigment that contributes color but is not an active drug.

(3) *Effectiveness.* Calamine is an effective protectant by virtue of its physical qualities, and its effectiveness is the same as that of zinc oxide (Refs. 1, 2, and 3). (See part V. paragraph B.1.M.(3) below—Effectiveness.) Because of this similarity, the Panel concludes that when zinc oxide and/or calamine are present in an anorectal drug product only one of the two substances shall be identified as an active ingredient. Calculations for protectant content must also reflect the total amount of zinc oxide, but use of both forms of zinc oxide constitutes only one protectant ingredient with respect to the combination policy. (See part II. paragraph K. above—Principles Applicable to Combination Products.)

(4) *Dosage.* Adult external and intrarectal dosage is 5 to 25 percent per dosage unit (based on the zinc oxide content of calamine and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

References

(1) Gosselin, R. E., et al., "Clinical Toxicology of Commercial Products. Acute Poisoning," 4th ED., The Williams and Wilkins Co., Baltimore, MD, p. 98, 1969.

(2) "The Merck Index," 8th Ed., Merck and Co., Inc., Rahway, NJ, p. 189, 1968.

(3) "The United States Dispensatory," 27th Ed., Edited by Osol, A. and R. Pratt, J. B. Lippincott Co., Philadelphia, PA, pp. 208–209, 1973.

(4) "The United States Pharmacopeia," 19th Rev., The United States Pharmacopoeial Convention, Inc., Rockville, MD, p.60, 1975.

c. *Cocoa butter (external and intrarectal use).* The Panel concludes

that cocoa butter is safe and effective as a protectant in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Cocoa butter is the fat obtained from the roasted seed of *Theobroma cocao.* Chemically it is a mixture of sterin, palmitin, olein, laurin, linolein, and traces of other glycerides. It is a yellowish-white solid with faint, agreeable odor and a bland chocolate-like taste. It is brittle below 25 degrees C. Cocoa butter possesses the remarkable property of maintaining its firmness within a few degrees of body temperature at which it readily melts without passing through an appreciable softening stage (Refs. 1 and 2).

(2) *Safety.* While no reports regarding the safety of cocoa butter in anorectal preparations have been found, the Panel recognizes that its safety has been established by its wide and continuous use in pharmacy and cosmetics (Refs. 1, 2, and 3).

(3) *Effectiveness.* Due to its bland, nonirritating properties, cocoa butter is considered to be an excellent protectant (emollient) for application to abraded or irritated anorectal tissue. In addition, it also acts as a protectant by providing a physical barrier against further contact by possible irritants (Ref. 4).

These properties, combined with the fact that it is considered to be a good vehicle for active drugs, are the reasons for its extensive use in suppositories (Ref. 5).

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

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d. *Cod liver oil (external and intrarectal use).* The Panel concludes that cod liver oil is safe and effective as a protectant (emollient) in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement and not to exceed a maximum daily dose of 10,000 International Units (IU) vitamin A and 400 IU vitamin D.

Description. Cod liver oil is the fixed oil, partially destarinated, obtained from fresh livers of *Gadus morrhua Linne* and other species of the Family *Gadidae.* Each gram contains not less than 255 μg (850 IU) of vitamin A and not less than 2.12 μg (85 IU) of vitamin D, the latter principally being activated 7-dehydrocholesterol or vitamin D_3. The glyceride components of the oil are principally of unsaturated acids, including arachidonic, clupanodonic, linoleic, linolenic, oleic, zoomaric, and other acids. The oil also contains cholesterol. Cod liver oil is subject to rancidity, and the vitamin A is easily oxidized (Refs. 1 and 2).

(2) *Safety.* While reliable and adequate scientific data regarding the safety of cod liver oil when applied to the anorectal area are not available, an extensive review of the literature on cod liver oil reveals no adverse affects when applied topically as a protectant (emolient) (Refs. 3 through 10). Because cod liver oil is assayed in terms of its vitamin A and vitamin D content, the Panel considered the applicability of the safety data of these ingredients as discussed elsewhere in this document and noted safe limits of vitamins A and D are not exceeded by the recommended dosage of cod liver oil. (See part VIII. paragraph B.3.e. (2) below—Safety and part VIII. paragraph B.3.f. (2) below—Safety.) The Panel concludes that cod liver oil is safe at the recommended dosage for application as a protectant to the anorectal area.

(3) *Effectiveness.* The Panel concludes that the effectiveness of cod liver oil as a protectant (emollient) is due to its bland and soothing effect associated with its oily nature.

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement and not to exceed 10,000 IU vitamin A and 400 IU vitamin D per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1 below—Category I Labeling.).

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e. *Glycerin in aqueous solution (external use).* The Panel concludes that 20 to 45 percent glycerin in aqueous solution is safe and effective as a protectant in OTC anorectal preparations when used in concentrations of at least 50 percent per dosage unit (200 to 450 mg in water to make 1 g) and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Glycerin is a clear, colorless, syrupy liquid, having a sweet taste. It is miscible with water and alcohol but insoluble in chloroform, ether, and in fixed and volatile oils (Ref. 1).

(2) *Safety.* The Panel concludes that glycerin is safe in OTC anorectal preparations. A review of the literature reveals no reports of adverse reactions or irritation to glycerin when used in anorectal preparations.

Glycerin has been administered orally and intravenously with relative safety (Ref. 2). The LD_{50} after oral administration is about 25 g/kg of body weight (Ref. 3), and 5 or 6 g/kg following intravenous administration (Ref. 4). The exact oral toxic dose of glycerin in humans has not been established. In humans, 100 to 300 g of pure glycerin have caused severe symptoms such as

destruction of red blood cells, reddish discoloration of the urine, and kidney failure, but these symptoms can be prevented and are a function of concentration and route of administration. Humans have been given about 100 g daily for 50 days with no ill effects (Ref. 5). Deichmann (Ref. 5) has concluded from a review of animal studies that toxic doses were the largest by the oral route and that the quantity necessary to produce toxicity varied with the mode of administration. The dose needed with the intraperitoneal route was the lowest, and the dose needed with the subcutaneous route was intermediate in toxicity.

The effects of local application of glycerin have been studies using a variety of methods. The immersion of rat's tails in undiluted glycerin produced no changes in the skin (Ref. 4). Application of undiluted glycerin to the conjunctiva of rabbits, cats, and dogs caused no visible changes (Ref. 4). No visible changes were noted following administration of glycerin to the oral mucous membranes of rats, rabbits, and dogs or of the mucous membranes of the stomach in rabbits and dogs (Ref. 4). However, when applied in the rectum of rats and guinea pigs, glycerin caused an accelerated emptying of the intestinal contents (Ref. 4). Studies regarding the skin irritating properties of natural or synthetic glycerin following application to the shaven rabbit dorsal area, (approximately 30 percent of the body surface) indicated that neither skin irritation nor any other abnormalities resulted from topical application of either synthetic or natural glycerin (Ref. 4). These studies (Ref. 4) suggest that glycerin was not absorbed in sufficient quantities to produce a pharmacologic effect.

According to Deichmann (Ref. 6) and Deichmann and Gerarde (Ref. 7), repeated and extensive applications of gylcerin, alone or in 50 percent aqueous solutions, upon the skin of rabbits and rats caused a mild irritation but did not induce definite or fatal intoxication. It has been reported that undiluted gylcerin absorbs water and is somewhat dehydrating and irritating to mucous membranes and particularly to inflamed or sunburned skin (Ref. 8). Therefore, a lower concentration is necessary for safe use in OTC anorectal preparations. There are no reports of reactions with 45 percent concentrations. Hine et al. (Ref. 3) reported that neither natural nor synthetic gylcerin gave evidence of toxic effects. Therefore, the Panel concludes that aqueous solutions of gylcerin in a 20 to 45 percent concentration are safe.

(3) *Effectiveness.* The dehydrating and osmotic actions and gylcerin have been utilized in preparations for local application to furuncles and other inflammatory processes (Refs. 9 through 12). However, this dehydrating effect is most pronounced when glycerin is used undiluted (Ref. 13). Keratin, as represented by a piece of callus, did not show any decrease in brittleness even when 0.1 mL water was added to 4 mL glycerin after 48 hours of exposure. Water alone reduced brittleness by 25 percent in 1 hour (Ref. 13). At best, the application of glycerin has been shown not to affect the ability of keratin to absorb water (Ref. 14). The significance of these findings related to anorectal use is that undiluted glycerin is not effective as a protectant, whereas a dilution of 20 to 45 percent glycerin in water, applied when the relative humidity of air is 30 percent or less as is often the case in winter, will lose water (Ref. 15) to epidermal tissue, and therefore, acts to soften the skin.

While no evidence of its protectant effect when applied to the anorectal area was found on the basis of its physical properties and frequent use as a protectant on the skin (Refs. 9, 10, 11, 16, 17, and 18), it is the Panel's conclusion that glycerin is effective as a protectant in the anorectal area.

(4) *Dosage.* Adult external dosage is 20 to 45 percent glycerin in aqueous solution when used in concentrations of at least 50 percent per dosage unit (200 to 450 mg in water to make 1 g) and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraphs B.1. below—Category I Labeling.)

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f. *Kaolin (external and intrarectal use).* The Panel concludes that kaolin is safe and effective as a protectant (adsorbent) in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Kaolin is a hydrated aluminum silicate, powdered and freed from gritty particles. It is a clay and occurs as a soft, white, or yellowish white powder (Ref. 1).

(2) *Safety.* There are no specific data regarding the safety of kaolin in the treatment of anorectal disorders; however, it is generally considered safe as a protectant (adsorbent) due to the inert nature of aluminum silicate, which is the primary chemical basis of kaolin (Refs. 2, 3, and 4).

(3) *Effectiveness.* Adequately controlled clinical studies demonstrating the effectiveness alone are not available, but the Panel recognizes the value of kaolin as a topical adsorbent based on its extensive use with aluminum hydroxide (Refs. 5, 6, and 7).

Studies confirm its ability to adsorb some drugs (Refs. 8, 9, and 10). It is also considered that kaoline adsorbs some toxins, bacteria, and viruses and is said to provide a protective coating for the intestinal mucosa (Ref. 2). In addition to adsorbing bacteria and various toxins, it has been suggested kaolin may act to increase the resistance to flow by solidifying the colonic contents (Ref. 3), but this has not been demonstrated, as discussed in the proposal to establish monographs for OTC Laxative, Antidiarrheal, Emetic, and Antiemetic products published in the Federal Register of March 21, 1975 (40 FR 12928).

As a protectant in combination with aluminum hydroxide, it has been successfully used in such highly irritated wounds as dermatitis, where there is an associated seepage of moist material (Refs. 5 and 6). These studies also indicate the need for specific labeling identified below. Kaolin may also be used as a pharmaceutical necessity to modify the consistency of anorectal preparations (Refs. 2, 3, and 11).

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the following specific labeling:

(i) *Indications.* (a) "For the temporary relief of itching associated with moist anorectal conditions."

(b) "Temporarily protects irritated areas from irritating materials."

(ii) *Warning.* (a) "Remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area."

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g. *Lanolin (external and intrarectal use).* The Panel concludes that lanolin is safe and effective as a protectant (emollient) in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Lanolin is a mixture of components from sheep sebum (Ref. 1) which include wool fat, waxes, and alcohols, as well as constituent esters, fatty acids, and aliphatic alcohols (Ref. 2). The relative amounts of these constituents vary with species of sheep and environment (Ref. 1) as well as with methods of processing. Concentrated lanolin is customarily mixed with 25 to 30 percent water to produce hydrous wool fat (Ref. 3). This material is widely used in medicine and cosmetics as an emollient base or emulsifier for topically applied products (Ref. 4).

(2) *Safety.* Although the toxicity of lanolin in anorectal products has not been determined, the major safety consideration relates to the allergenicity of this heterogeneous mixture when applied to any skin site (Refs. 5 through 13). Although the primary allergic manifestations to topical lanolin is localized dermatitis, systemic manifestation have also been reported (Ref. 9). The incidence of allergic manifestations to topical lanolin in dermatology clinics has been reported to be 1.04 to 1.7 percent (Refs. 5, 7, 8, and 10), but the incidence in the general population is thought to be lower (Ref. 10). Studies have shown that the wool alcohol fraction is the most allergenic (Refs. 1, 2, and 7) and that acetylation or alkylation of the alcohol fraction eliminates this property (Refs. 2 and 8). While there is at least 1 report of allergy to hydrogenated lanolin, more recent data indicate that allergenicity is not a significant problem (Refs. 14 and 15).

In data presented to the Panel citing studies of the International Contact Dermatitis Research Group, the incidence of lanolin allergy was reported to be extremely low (Ref. 15). Further, the patients who were sensitized to lanolin usually had chronic eczema or leg ulcers. Females were found to be more sensitive to lanolin than males. Six physicians reported no allergic reactions to lanolin when it was applied to the anorectal area. The allergenicity of lanolin appeared to be dose related.

The Panel, therefore, concludes that although lanolin will cause allergic reactions or sensitize same patients, it can be used safely by the major portion of the OTC target population and that a warning for safe use is not necessary.

Systemic toxicity due to absorption of lanolin at the anorectal site has not been determined. When applied topically to rat skin, only a small amount of lanolin is absorbed (Ref. 13); the Panel therefore concludes that there is probably no significant systemic toxicity from lanolin use in anorectal products. With regard to direct skin safety, one report of the absence of histological changes after repeated lanolin applications has been made (Ref. 16). However, because there is a tendency for emollients to cause folliculitis in hairy skin areas or in areas subject to friction or sweating (as in the anorectal area), there is a possibility that lanolin could also produce this effect in some persons. Lanolin has been shown to alter the percutaneous (unbroken skin) absorption of certain compounds (Refs. 17 and 18) so that it can potentially increase or decrease the absorption of active ingredients in anorectal products. The Panel does not deem this effect to diminish the safety of anorectal products with lanolin.

(3) *Effectiveness.* No studies can be found substantiating the use of lanolin in the treatment of anorectal lesions. One study, involving the surface of the forearm, demonstrated the ability of petrolatum to reduce moisture loss (Ref. 19). The Panel concludes that lanolin exhibits much the same properties as petrolatum and, therefore, would have the same type of reduction in moisture loss. However, the Panel concludes that, based on the multitude of dermatologic preparations containing lanolin and the widespread use of lanolin over the centuries, lanolin is effective as a protectant (emollient) (Ref. 20).

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

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h. *Mineral oil (external and intrarectal use).* The Panel concludes that mineral oil is safe and effective as a protectant in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Mineral oil is a nonvolatile mixture of hydrocarbons (Ref. 1) which is derived from crude petroleum and contains a suitable stabilizer. It is an odorless, colorless, transparent, oily liquid, insoluble in water and alcohol, but soluble in most volatile oils (Ref. 2). Chemically, it is relatively inert. It does not undergo deterioration and cannot become rancid or irritating (Ref. 3). It is widely used externally as an emollient or vehicular aid in creams and suppositories (Ref. 4).

(2) *Safety.* No reports relating to the toxicity or safety of mineral oil in anorectal preparations were found.

In the crude state the precursors of mineral oil and related petroleum derivative medicinals potentially contain a number of polycyclic aromatic hydrocarbons, some of which are carcinogenic. Any statement as to safety is predicated on the assumption that all manufacturers use adequately refined and tested petroleum derivatives that meet established standards of identity and purity (Refs. 5 and 6).

Mineral hydrocarbons, although physically resembling other organic liquids, are not subject to metabolism and can thus remain on the skin indefinitely unless physically removed. They are not absorbed through the skin but may penetrate into hair follicles and glands (Ref. 3); more specifically, liquids, more rapidly than solid fat, can be demonstrated microscpically in lymph channels (Ref. 3). True fats are oxidized, but mineral fats remain and can produce chronic irritation fibrosis and foliculitis. This phenomenon has been amply demonstrated in the many reports of paraffinomas after injection or installation of mineral oil or paraffin into tissues (Refs. 7, 8, and 9). A more relevant report of this occurrence after use of mineral oil as a lubricant for dilation and curettage is available (Ref. 9), which suggests that repeated application of mineral oil hydrocarbons to fissured anal areas or to raw mucosa could result in a similar problem. However, the Panel concludes that, when used as recommended, mineral oil is safe for use in anorectal products.

(3) *Effectiveness.* No studies were found relative to the topical effectiveness of this agent in anorectal disease. However, by extrapolation from use on other parts of the body and by virtue of its physical properties, the Panel concludes that mineral oil is effective as a protectant. A layer of mineral oil is less effective than petrolatum in reducing moisture loss from the outer layer of the skin of the forearm, but it is significantly greater than other materials tested (Ref. 10). This property is also interpreted by the Panel to provide occlusion of the area from external exposure to air, liquids, or other substances within reasonable limits.

Because it is not absorbed, its effect may be prolonged for hours until it is physically removed. The effectiveness of mineral oil and analogous petroleum-derived agents such as lubricants, protective agents, and stable vehicles must be weighed against potential accumulation and persistence until physically removed.

Experimental evidence exists that suggests that mineral oil and related hydrocarbons may definitely influence the absorption of agents with which they are mixed, usually by preventing absorption, but in some cases promoting it (Refs. 11, 12, and 13). Mineral oil is thus capable of rendering an effective combination of agents relatively ineffective.

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

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i. *Shark liver oil (external and intrarectal use).* The Panel concludes that shark liver oil is safe and effective as a protectant (emollient) in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement and not to exceed a maximum daily dose of 10,000 IU vitamin A and 400 IU vitamin D.

(1) *Description.* Shark liver oil is an amber to brown oily liquid that contains a mixture of glyceryl esters of fatty acids and other substances, including vitamins A and D. Its content of vitamin A and D may vary but is usually measured in terms of International Units (IU). In the past the oil was assayed biologically and required to have potency of not less than 16,500 IU/g of vitamin A and not less than 40 IU/g of vitamin D (Refs. 1, 2, and 3). Currently, there is no official standard for shark liver oil.

(2) *Safety.* A search of the literature reveals no reports of adverse or toxic reactions to shark liver oil or any controlled clinical studies regarding its safety, but there is ample literature in regard to vitamins A and D. There are no data to confirm that vitamins A and D in shark liver oil are not absorbed. Until such data are available, the Panel concludes that a reasonable maximum allowable concentration for safe OTC topical use is 10,000 IU of vitamin A and 400 IU of vitamin D. Because shark liver oil has been used externally without any known reported local or systemic adverse reaction, the Panel concludes that it is safe, when used as directed, as a protectant for anorectal use.

(3) *Effectiveness.* While no studies relative to the effectiveness of shark liver oil as an individaul ingredient in the treatment of anorectal disease were found, fish liver oils can be considered as having generally similar properties (Ref. 4). Therefore, studies and reports on cod liver oil (Ref. 5) provide a basis and support for extrapolation to the effectiveness of shark liver oil. The Panel concludes that shark liver oil is effective as protectant by coating the area to which it is applied. When used as recommended, it relieves mild irritation of the anorectal area due to its soothing and protective effect associated with its oily nature.

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement and not to exceed 10,000 IU vitamin A and 400 IU vitamin D per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

References

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j. *Starch (external and intrarectal use).* The Panel concludes that starch is safe and effective as a protectant (absorbent) in OTC anorectal products in concentrations of at least 50 percent per dosage unit and not be exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Starch is a crystalline polymeric compound involving linear and branch chain structures of amylose and amylopectin which may be derived from corn or rice (Refs. 1 and 2).

(2) *Safety.* Starch is an insoluble substance and chemically inert. In one study the toxic effects of starch following oral intake have been described. Of the various foodstuffs investigated, starch is by far the least toxic (Ref. 3). Starch in the peritoneal cavity following surgery has produced granulomas, but no toxicity has been reported from topical use on the skin or in the anorectal area. Considering the wide-spread use of starch as a food, the Panel considers these adverse reports as not applicable to OTC anorectal products.

(3) *Effectiveness.* Starch acts by preventing friction and/or by absorbing moisture (Refs. 4 and 5). Talcum is often used in baby formulations (Ref. 5). The Panel concludes that the physical properties of starch are sufficiently similar to talcum so that starch could replace talcum in some baby formulations. The Panel concludes that starch is effective as a protectant to cover the anorectal area and may relieve symptoms of burning, pain, or itch associated with mild irritation (Ref. 6). Because moistened starch can support bacterial growth, it should be washed off before reapplication.

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

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(3) Boyd, E. M. and S. J. Liu, "Toxicity of Starch Administered by Mouth," *Canadian Medical Association Journal,* 98:492–499, 1968.

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(5) Barnett, G., "Baby Toiletries," *in* "Cosmetics, Science and Technology," Volume I, Edited by Balsam, M. S. and E. Sagarin, John Wiley and Sons, Inc., New York, pp. 120–135, 1972.

(6) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1032, 1971.

k. *White petrolatum (external and intrarectal use).* The Panel concludes that white petrolatum is safe and effective as a protectant (emollient) in OTC anorectal preparations in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Petrolatum (white petrolatum) is a purified mixture of semisolid hydrocarbons obtained from petroleum. A suitable stabilizer may be present. It is a yellowish to light amber unctuous mass. When petrolatum is

treated to remove color, the product is white or faintly yellowish and is officially recognized as white petrolatum (Ref. 1). The uses of white petrolatum are similar to those of petrolatum, but the former is usually preferred over the latter when an ointment of light color is desired.

(2) *Safety.* The safety of petrolatum has been established by its continuous use for almost a century in pharmacy and cosmetics. Also, petrolatum has been prescribed for many decades as a base for anorectal medications.

Some questions have been raised regarding the safety of prolonged and repeated contact of petrolatum with the skin. These questions involve allergenic and carcinogenic potential. The Panel has reviewed the data and concludes that, when petrolatum did not meet the standards as set forth in the official compendia, impurities were the cause of these safety problems (Refs. 2, 3, and 4). When purified grades were investigated by feeding studies on rats and implantation studies on mice, petrolatum was found to be nontoxic, noncarcinogenic, and innocuous in character (Refs. 2, 3, and 4). An unpublished study involving a total of 54 human subjects utilizing a repeated insult patch test procedure indicated that there was essentially no irritation or reaction (Ref. 5). On the basis of the evidence available, the Panel concludes that petrolatum of the purity and quality as set forth in the official compendia (Ref. 1) is safe for application to the anorectal region when used in the recommended dosage. The ability of petrolatum to provide an optimal occlusive surface serves as a model against which other ingredients can be measured as shown by Berube, Messinger, and Berdick (Ref. 6).

(3) *Effectiveness.* Petrolatum applied topically is widely recognized and accepted as a protectant (emollient). Its desirable physical properties and innocuous nature are factors promoting its use as a physical barrier. In the judgment of the Panel, petrolatum serves to reduce further effects of irritants on the affected anorectal area and may relieve burning, pain, or itch produced by these irritants.

The technique of evaluating protectants has been demonstrated utilizing the ability of specific dyes to penetrate a film of ointment which confirms that irritants can be prevented from reaching the epidermis (Ref. 7). Measurement of the actual protection of normal skin surface against contact with water by various ointments showed that white petrolatum was the most effective protectant in 25 of 32 tests (Ref. 8).

(4) *Dosage.* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below-Category I Labeling.

References

(1) "The United States Pharmacopeia," 19th Rev., The United States Pharmacopeial Convention, Inc., Rockville, MD, 1975.
(2) OTC Volume 120012 pp. 7–13.
(3) OTC Volume 120012 pp. 19–20.
(4) OTC Volume 120012 pp. 44–51.
(5) OTC Volume 120012 pp. 87–97.
(6) Berube, G. R., M. Messinger and M. Berdic, "Measurement In Vivo of Transepidermal Moisture Loss," *Journal of the Society of Cosmetic Chemists*, 22:361–368, 1971.
(7) OTC Volume 120063.
(8) Steigleder, G. K. and W. P. Raab, "Skin Protection Afforded by Ointments," *Journal of Investigative Dermatology*, 38:129–131, 1962.

1. *Wool alcohols (external and intrarectal use).* The Panel concludes that 4 to 7 percent wool alcohols per dosage unit not to exceed six applications per 24 hours or after each bowel movement effective as protectants (emollients) in OTC anorectal preparations are safe.

(1) *Description.* Wool alcohols are constituents of lanolin, which is obtained from sheep sebum (Refs. 1 and 2), and consist of a mixture of aliphatic alcohols (Ref. 2). Wool alcohols can be used as protectants (emollients) or as a pharmaceutical necessity for various pharmaceutical formulations.

(2) *Safety.* The systemic toxicity of wool alcohols administered by any route is not known but is presumed to be low. (See part V. paragraph B.1.g.(2) above—Safety.) Wool alcohols do cause allergic reactions and are believed to be the cause in most cases of lanolin allergy (Refs. 1 and 3). The percentages of wool alcohols that are safe and effective shall not exceed the 4 to 7 percent occurring naturally in lanolin (Res. 4, 5, and 6). The incidence of such allergy to lanolin is questionable (Refs. 3, 7, 8, and 9), but more recent data indicate that allergencity is not a problem among the general population (Ref. 10) using topical preparations according to the recommended dosage. Reportedly, acetylation of wool alcohols decreases allergencity (Refs. 3 and 9), and such treatment should be considered if wool alcohols are separated from lanolin before they are incorporated into OTC drug products.

(3) *Effectiveness.* Wool alcohols are similar in pharmacologic effect to lanolin. The Panel concludes that wool alcohols are effective as protectants (emollients) (Ref. 11) at the 4 to 7 percent concentration naturally occurring in lanolin. (See part V. paragraph B.1.g.(3) above—Effectiveness.) No studies of effectiveness with regard to anorectal use have been found.

(4) *Dosage.* Adult external and intrarectal dosage is 4 to 7 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I labeling.) In addition, the Panel recommends the following specific warning when the wool alcohols have been added to the final formulation as separate ingredients: "*Caution:* Certain persons can develop allegic reactions to ingredients in this product. If redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician."

References

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(2) OTC Volume 120067.
(3) Evans, S., "Epidermal Sensitivity to 'Lanolin' and 'Parabens': Occurrence in Pharmaceutical and Cosmetic Products," *British Journal of Dermatology*, 82:625, 1970.
(4) Warth, A. H., "The Chemistry and Technology of Waxes," Reinhold Publishing Inc., New York, 1956.
(5) Truter, E. V., "Wool Wax, Chemistry and Technology," Interscience Publishers, Inc., New York, 1956.
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(9) Warshaw, T. G., "On the Incidence of Allergic Skin Reaction to Lanolin to Its Components, and Certain Lanolin Modifications," *Journal of the Society of Cosmetic Chemists, 4:290–296, 1953.*
(10) Minutes of the OTC Panel on Hemorrhoidal Drug Products, 23d meeting, November 21, 22, and 23, 1976.
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m. *Zinc oxide (external and intrarectal use).* The Panel concludes that 5 to 25 percent zinc oxide per

dosage unit is safe and effective as a protectant for use in OTC anorectal preparations and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Zinc oxide is one of a class of bertholide compounds in which the ratio of zinc to oxygen is not exactly 1:1; a property which results in some chemical instabilities (Ref. 1). It is water insoluble, but it is soluble in weak acids and in the presence of fats and tends to form other zinc compounds (Refs. 1, 2, and 3). It will absorb only very small amounts of water (Ref. 4). It is widely employed in a number of dermatologic conditions as an astringent and protective and is often employed as an ingredient of a basic ointment for incorporation of other drugs (Refs. 1 through 5).

(2) *Safety.* Zinc oxide has long been regarded as a relatively nontoxic substance when used both topically and orally (Refs. 5 and 6). Although the oxide is supposed to be inert and not absorbed, it is not completely chemically stable so that free zinc or zinc ions may be available (Ref. 1). However, no specific data are available. It is probable that even if moderate amounts are absorbed systemically they will not exert deleterious effects because zinc is an essential trace metal with 10 to 15 mg daily a part of a normal diet (Refs. 7, 8, and 9) and there are sufficient metabolic mechanisms to cope with increased zinc on at least a short term basis (Ref. 9).

Acute systemic zinc toxicity is manifested by nausea, vomiting, lethargy, and severe pain (Refs. 6 and 10). Chronic toxicity is manifested by anemia and porotic bone changes (Ref. 11). Zinc toxicity relates primarily to amounts greater than 1 g zinc sulfate (Ref. 12) and does not appear to relate to topical applications of zinc or zinc compounds except possibly, although unlikely, from very long-term use. Further, no reports of a direct irritant effect or allergenic effects of zinc oxide were found. Therefore, the Panel concludes it is safe for use in the anorectal area when used as recommended.

(3) *Effectiveness.* Zinc oxide is widely used by dermatologists as a paste to absorb excess moisture and secretions on acute lesions where there is a tendency for vesiculation, oozing, or crusting (Refs. 13 and 14). The Panel concludes that zinc oxide powder forms a protective coating on inflamed areas, and can be an effective protectant (absorbant) in anorectal therapeutics. A study by Steigleder and Raab (Ref. 15) substantiates a protective effect of skin surface against contact with water afforded by 20 percent zinc oxide in 13 of 20 tests. The Panel concludes that in combination a concentration of 5 to 25 percent zinc oxide per dosage unit is necessary to exert a protectant effect.

(4) *Dosage.* Adult external and intrarectal dosage is 5 to 25 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. below—Category I Labeling.)

References

(1) Fryer, F. A., "Cosmetic Applications of Zinc Compounds. Chemical and Biological Considerations," *Soap, Perfumery and Cosmetics,* 42:343–347, 1969.

(2) "The Dispensatory of the United States of America," 25th Ed., Edited by Osol, A. and G. E. Farrar, Jr., J. B. Lippincott Co., Philadelphia, PA, pp. 1515–1517, 1955.

(3) "Martindale. The Extra Pharmacopoeia," 25th Ed., Edited by Todd, R. G., The Pharmaceutical Press, London, England, p. 1490, 1967.

(4) Goodman, L. S. and A. Gilman, "Pharmacologic Basis of Therapeutics," 4th Ed., The Macmillan Co., New York, p. 989, 1970.

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(13) Swinyard, E. A. and S. C. Harvey, "Topical Drugs," *in* "Remington's Pharmaceutical Sciences", 13th Ed., Edited by Martin, E. W., Mack Publishing Co., Easton, PA, p. 851, 1965.

(14) "The United States Dispensatory Physicians' Pharmacology," 26th Ed., Edited by Osol, A., R. Pratt and M. D. Altschule, J. B. Lippincott Co., Philadelphia, PA, p. 1246, 1967.

(15) Steigleder, G. K. and W. P. Raab, "Skin Protection Afforded by Ointments," *Journal of Investigative Dermatology,* 38:129–131, 1962.

Category I Labeling

The Panel recommends the following Category I labeling for protectant active ingredients to be generally recognized as safe and effective and not misbranded.

a. *Indications.* (1) "Forms a protective coating over inflamed tissues which can relieve itching."

(2) "Aids in the relief of itching or anorectal discomfort."

(3) "Temporarily forms a protective coating over inflamed tissues which helps prevent drying of tissues."

(4) "Temporarily protects irritated areas from irritating materials."

(5) "Temporarily relieves anorectal itching."

(6) "temporarily relieves burning."

(7) "Provides temporary relief from skin irritations."

(8) "For the temporary relief of itching associated with hemorrhoids, inflamed hemorrhoidal tissue or other anorectal disorders."

(9) "For the temporary relief of local itching associated with hemorrhoids, inflamed hemorrhoidal tissues, or other anorectal disorders."

(10) "For the temporary relief from itching and discomfort due to hemorrhoids or other anorectal disorders."

(11) "Temporarily provides a bland, soothing coating for relief of anorectal discomforts."

(12) "Temporarily provides lubrication in the anorectal area."

(13) "Temporarily lubricates and protects the inflamed irritated anorectal surface to help make bowel movements less painful."

(14) "Temporarily protects from irritation and abrasion during bowel movement."

(15) "Temporarily helps soften and lubricate dry inflamed perianal skin."

(16) "Temporarily relieves the symptoms of perianal skin irritation, and itching."

(17) "Provides lubrication and may help make bowel movements more comfortable."

2. *Category II conditions under which protectant ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredient

The Panel has classified the following protectant active ingredient as not generally recognized as safe and effective or as misbranded:

Bismuth subnitrate (external and intrarectal use). The Panel concludes that bismuth subnitrate is not safe for

use in OTC anorectal products as a protectant.

(1) *Description.* Bismuth subnitrate, also called bismuth oxynitrate, Spanish white, and bismuth paint, is a white, odorless, slightly hygroscopic, almost tasteless powder (Refs. 1 and 2).

(2) *Safety.* There is little information regarding the safety of bismuth subnitrate in the treatment of anorectal disease but significant data regarding poisoning by its local application and/or ingestion. The absorption of bismuth salts through application to open surfaces has been shown in animal and human studies to cause severe ulceration of oral and pharyngeal mucous membranes as well as necrotic, purplish lesions throughout the intestinal tract (Ref. 3). Subcutaneous injections in dogs have produced the same results. Experiments with certain other salts of bismuth have produced the same changes. Thus the repeated symptoms and lesions found in humans and experimentally produced in animals show these toxic effects are due to metallic bismuth (Ref. 3). The signs and symptoms of bismuth intoxication are stomatitis, ulceration, gingival diphtheritic type lesions, dysphagia, nephritis, nausea, and diarrhea (Refs. 1 and 3).

Though most inorganic nitrates are poorly absorbed from the gastrointestinal tract, nitrites, are well-absorbed (Ref. 1). Bismuth subnitrate is converted to nitrite in the presence of bacteria normally found in the bowel such as *E. coli* (Refs. 1 and 4). Because of this change, the action of nitrates and nitrites, especially on smooth muscles, are frequently indistinguishable and the term "nitrite" historically refers to nitrites and nitrates (Ref. 1). The basic action and most common effect of nitrite is its ability to cause dilatation by relaxing smooth muscles, especially those in the arterioles and capillaries. Its ability to relax blood vessels and other organs is independent of nerve supply (Ref. 1). This results in increased rate of capillary blood flow being more effective in the postarterial lower vascular bed. There is a subsequent fall in blood pressure, and thus nitrites, in doses of 65 mg three times daily, were an early treatment for hypertension. The signs and symptoms of nitrite intoxication are vomiting, convulsions, dizziness, sleepiness, methemoglobinemia, and cardiovascular collapse (Refs. 1, 2, and 3). Methemoglobinemia is a condition in which the oxygen is fixed to the hemoglobin in the red blood cell by oxidizing substances such as nitrites, and therefore, cannot be released in the tissues. Unless treated, it can lead to death due to oxygen starvation of the body tissues.

The use of bismuth subnitrate in current times is rare. Due to its spasmolytic (relaxing) effect on blood vessels, bismuth subnitrate has been used for treatment of angina (chest pain due to decreased oxygen to heart) and for high blood pressure. It has also been used as a protectant (adsorbent) in the treatment of diarrheas, intestinal inflammation, and ulcerations (Ref. 1). Through the conversion of bismuth nitrate to nitrite by the presence of *E. coli* in the intestinal tract, the danger arises of absorption of excess amounts of nitrites leading to toxic effects. In children, this is even more dangerous because *E. coli* organisms are commonly found in the upper as well as the lower gastrointestinal tract. Bismuth subnitrate intoxication presents a classic case of methemoglobinemia (Ref. 3), and its frequency of occurrence in children has led physicians not to prescribe this compound for patients under the age of 15 (Ref. 5). This toxic reaction is less common in adults, but since 1935 at least six cases have been reported (Refs. 1 and 3). Three cases, reported out of emergency rooms, would suggest that this type of intoxication is more common than believed and that the less severe reactions probably go unreported by patients and physicians (Refs. 1 and 3). In these three cases, intoxication followed the use of bismuth subnitrate in the treatment of jejunitis, hypochlorhydric gastritis, and inflammation of the bowel, with a 20 g dose in one case administered over 24 hours (Ref. 5). By instillation of bismuth subnitrate directly into the colon, nitrite methemoglobin is produced quickly. A significant number of cases have been reported of methemoglobinemia, including death, in children following ingestion of drinking water (Ref. 6) and local application of dusting powders (Ref. 1). Methemoglobinemia, headaches, and cardiovascular collapse have been reported in adults. Therefore, this compound cannot be considered safe and its toxic effects should prohibit the use of this compound for OTC drug preparations.

(3) *Effectiveness.* Bismuth salts have been used as a protectant (Refs. 1 through 4). There is no evidence that bismuth subnitrate is more effective than other protectant ingredients which are not associated with a safety problem.

(4) *Evaluation.* The Panel concludes that bismuth toxicity can be caused by bismuth subnitrate. Of greater concern than bismuth toxicity is the possibility of nitrite toxicity due to the conversion of nitrate to nitrite in the presence of bacteria normally found in the colon and rectum. The Panel concludes, due to the rapid absorption of nitrites across mucous membranes, that bismuth subnitrate is not safe for use in OTC anorectal products.

References

(1) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 2d Ed., The Macmillian Co., New York, pp. 730–743, 1955.

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Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of protectant drug products are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel considers the following claims to be misleading and unsupported by scientific data:

a. "Promotes wound healing." There is no evidence that wound healing is promoted, i.e., proceeds at more than the normal rate.

b. "For temporary relief of inflammation." Inflammation can occur as a result of perirectal abscess, which would not be relieved by such products. This claim is too broad.

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredients

The Panel concludes that the available data are insufficient to permit final classification of the following protectant active ingredients listed below. The Panel believes it reasonable to provide 2 years for the development and review of such data. Marketing

need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed in OTC products:

Bismuth oxide (external and intrarectal use)
Bismuth subcarbonate (external and intrarectal use)
Bismuth subgallate (external and intrarectal use)

a. *Bismuth oxide (external and intrarectal use).* The Panel concludes that bismuth oxide is safe for use as a protectant in OTC anorectal preparations, but there is insufficient evidence to prove effectiveness.

(1) *Description.* Bismuth oxide occurs in nature as the mineral bismite. It is a yellow, ordorless powder that is insoluble in water (Ref. 1).

(2) *Safety.* No untoward effects of bismuth oxide have been reported in the available literature. However, the effects are theoretically similar to those of bismuth subcarbonate because they are nearly equally insoluble in water (Ref. 2). Bismuth subcarbonate is used orally in humans to coat the intestinal mucosa at a minimum dosage of 1 g four times daily. (See part V. paragraph B.3.b.(2) below—Safety.) This dosage is used to establish the upper limit of bismuth permitted anorectal preparations. Though absorption of bismuth subcarbonate has been proven in rabbits, the Panel has concluded that it is safe for short term use in human anorectal products at doses of bismuth salts equivalent to 1 g or less bismuth oxide daily. This upper limit may prevent any bismuth salt from meeting the requirement for a protectant in an anorectal drug product (i.e., at least 50 percent per dosage unit) but the Panel permits as many as three additional protectants to be combined so that any final formulation could easily meet the requirement for protectant if such a claim is made.

The lower limit, 17.5 mg bismuth oxide per dosage unit, is based on the lowest quantity present in any of the data submitted for review and does not, in the opinion of the Panel, present a hazard when used according to recommended dosage.

(3) *Effectiveness.* The local action of bismuth oxide probably is due to a mechanical effect of fine insoluble powder (Ref. 3). The properties theoretically are similar to those of bismuth subcarbonate for which the Panel has not found adequate data to support therapeutic claims. (See part V. paragraph B.3.b.(3) below—Effectiveness.)

(4) *Proposed dosage.* Adult external and intrarectal dosage is 17.5 to 166 mg per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* Data to demonstrate effectiveness as a protectant will be required in accordance with the guidelines set forth below for testing protectant ingredients. (See part V. paragraph C. below—Data Required for Evaluation.)

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b. *Bismuth subcarbonate (external and intrarectal use).* The Panel concludes that there is insufficient evidence to prove effectiveness of bismuth subcarbonate for use as a protectant in OTC anorectal preparations, but it is safe for use at the recommended dosage.

(1) *Description.* Bismuth subcarbonate is a white to yellow, odorless, tasteless powder which is stable in air but is slowly affected by light with the production of carbon dioxide and bismuth oxide. It is relatively insoluble in water and alcohol (Ref. 1).

(2) *Safety.* When absorbed in various amounts, bismuth can produce lesions of the kidney, liver, gastrointestinal tract and gums, and clinically can result in renal failure and death (Refs. 2, 3, and 4). Most reported cases of bismuth toxicity have been due to the water soluble bismuth salts such as bismuth ammonium citrate, bismuth tartrate, or bismuth subnitrate, administered either parenterally, orally, or topically (Refs. 4 through 9). However, leasions of the kidney have been noted in many patients who received the less soluble bismuth salts for antisyphilitic therapy (Refs. 10 and 11). Oral daily administration of 107 mg/kg of body weight bismuth subcarbonate in beagle dogs for 2 weeks resulted in bismuth deposits of 6 to 14 parts per million (ppm) in the kidneys, as compared to 35 to 115 ppm after the same dose of bismuth as a soluble salt, although no physiological abnormalities were noted. Therefore, it is probable that some bismuth may be absorbed from this relatively insoluble salt. The LD_{50} of bismuth for rabbits is approximately 200 to 400 mg/kg, although the nephrotoxic dose is 85 mg/kg or less (Ref. 12). Because bismuth tends to accumulate in certain tissues, especially kidney, and is only slowly eliminated (Refs. 11 and 13), exposure should be limited. The Panel concludes that bismuth subcarbonate is safe for short term use in OTC anorectal products at doses equal to bismuth oxide. (See part V. paragraph B.3.a.(2) above—Safety.)

(3) *Effectiveness.* The bismuth salts have been promoted as protectants, but no specific reports support this claim. Bismuth subcarbonate is stated to have protective, absorbent, and antacid properties, but experience suggests that none of these is of any great therapeutic importance (Ref. 14). Similar doubts are expressed elsewhere (Ref. 15). Further, one source suggests the therapeutic effectiveness of bismuth salts is dependent upon its solubility (Ref. 16). If this is true, then effectiveness may be correlated with increased toxicity. The purported healing effect of bismuth subcarbonate on inflamed mucous surfaces and wounds by drying the secretion and forming a protective covering or scab has not been clinically established. The local effect is probably due to the physical properties of a fine insoluble powder (Refs. 17 through 20). Bismuth subcarbonate is listed as a topical protectant in an official compendium (Ref. 1). The basis for claims as a protectant can only be reached by bismuth salts when combined with other protectants. (See part V. paragraph B.3.a.(3) above—Effectiveness.) The Panel concludes that there are insufficient data to support the suggestion that bismuth subcarbonate has any effectiveness as a protectant (absorbent) in anorectal products.

(4) *Proposed dosage.* Adult external and intrarectal dosage is 17.5 to 166 mg per dosage unit and not to exceed the equivalent of 1 g bismuth oxide in 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* Data to demonstrate effectiveness as a protectant will be required in accordance with the guidelines set forth below for testing protectant ingredients. (See part V. paragraph C. below—Data Required for Evaluation.)

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c. *Bismuth subgallate (external and intrarectal use).* The Panel concludes that there is insufficient evidence to prove effectiveness of bismuth subgallate as an ingredient for use in OTC anorectal preparations, but it is safe for use at the recommended dosage.

(1) *Description.* Bismuth subgallate is an alkaline salt composed of 46 to 52 percent elemental bismuth. It is practically insoluble in water, alcohol, and ether, and is stable in air, but slightly affected by light (Ref. 1). It has been promoted as an astringent, protectant, and absorbent, as well as an antibacterial agent, although proof of these properties is not found in the literature. It is also used as a bulk and stiffening agent in many suppository preparations.

(2) *Safety.* There are no known studies of the toxicity in animals or humans of bismuth subgallate as a single ingredient. Although the insoluble bismuth salts are reported to be relatively nontoxic (Ref. 2), the degree of toxicity of bismuth compounds varies with the salt used (Refs. 3 and 4), and no studies of this compound have been reported. Intramuscular injections of 200 mg of the moderately insoluble bismuth subsalicylate has produced proteinuria (Refs. 3 and 5), renal tubular damage, hepatic damage, stomatitis, and even death has been reported with high doses of various bismuth salts (Ref. 6). The LD_{50} for various bismuth compounds and metallic bismuth injected intramuscularly in rabbits is 200 to 400 mg/kg (Ref. 3), and a nephrotoxic dose in rabbits is 85 mg/kg. The maximum concentration at which no renal damage is seen has not been established for any of the bismuth salts. Although the topical application to granulating surfaces of the more soluble bismuth compounds has resulted in a number of cases of bismuth intoxication with some deaths (Ref. 7), the specific tolerance limits for mucous membrane and percutaneous absorption of bismuth subgallate has not been studied. Bismuth, reportedly, can be absorbed from topical sites by phagocytosis (Ref. 7) and may be absorbed as a more soluble salt formed either from reaction at the application site or with other constituents in the preparation (Ref. 8). Because bismuth is retained in the body for extended periods of time (Refs. 4 and 9), in a manner similar to lead, repeated use with any degree of absorption of any solubilized salt may result in accumulation. Therefore, the possibility, that chronic use of topical bismuth subgallate in the anorectal area may result in toxicity, forms the basis for dosage restrictions based on its safety. The Panel sets the upper limit at 166 mg per dosage unit, not to exceed 1 g per 24 hours.

(3) *Effectiveness.* Bismuth subgallate has not been shown to be effective as a therapeutic agent. Although numerous reports attest to the clinical effectiveness of suppositories containing bismuth subgallate (Refs. 10 through 14), these reports are primarily anecdotal and no controlled studies have been reported. Therefore, there is no evidence to confirm that this agent alone is responsible for alleviation of anorectal symptoms or that it has protectant (absorbent) effects. Bismuth subgallate is no longer listed in the standard compendia, and several sources share doubt as to its purported effectiveness (Refs. 11, 15, and 16). However, studies were not found to support either positive or negative proof of its effectiveness, although these studies could be carried out quite easily. The basis for claims as a protectant can only be reached by bismuth salts when combined with other protectants. (See part V. paragraph B.3.a. (3) above—Effectiveness.)

(4) *Proposed dosage.* Adult external and intrarectal dosage is 17.5 to 166 mg per dosage unit and not to exceed 1 g per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for protectant active ingredients. (See part V. paragraph B.1. above—Category I Labeling.)

(6) *Evaluation.* Data to demonstrate effectiveness as a protectant will be required in accordance with the guidelines set forth below for testing protectant ingredients. (See part V. paragraph C. below—Data Required for Evaluation.)

References

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Category III Labeling

The Panel concludes that the available data are insufficient to permit final classification of the following claims. Additional data are required to support the following protectant claims:

a. "Forms a protective coating which may allow healing to occur."

b. "May allow healing to occur by its protective action."

The evaluaiton of these claims must be aimed at "healing effects" if the ingredient for which the claim is made is a Category I protectant. "Healing" is not part of the evaluation of protectant ingredients. (See part VIII. paragraph C. below—Data Required for Evaluation.)

C. Data Required for Evaluation

The Panel has agreed that the protocols recommended in this document for the studies required to substantiate Category I are in keeping with the present state of the art and do not preclude the use of any advances or improved methodology in the future.

1. *Principles in the design of an experimental protocol for testing protectant drugs*—a. *General principles.* (1) Establish prevention of transepidermal water loss, or (2) establish ability of the product, through its application, to prevent substances (e.g. dyes and/or water) from contacting the anorectal tissues.

b. *Selection of patients.* (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

c. *Methods of study.* The details of the methods of study would be in accordance with those used in studies establishing the principles stated above, i.e.:

(1) Transepidermal water loss as studied by Berube, Messinger, and Berdick (Ref. 1). (See part V. paragraph B.1.k. above—White petrolatum (external and intrarectal use.)

(2) Prevention of penetration of dyes (Ref. 2).

(3) Prevention of penetration of water (Ref. 2).

(4) (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

d. *Interpretation of data.* A sufficient number of trials must be performed to provide statistically significant results within 7 days.

e. *Evaluation of study.* The testing described above is intended to establish effectiveness. The safety of protectants at dosage limits specified within this document do not require further testing unless new data indicate the need for reevaluation.

References

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VI. Counterirritants

A. General Discussion

A counterirritant is an agent that produces a local sensation that distracts from the perception of pain, burning, or itching. The perception of these symptoms is distracted and commonly replaced by the perception of warmth, cooling, or tingling sensations. Counterirritants have been used empirically for many centuries (Ref. 1).

Counterirritants in low concentrations are therapeutic. Counterirritants in high concentrations can produce severe irritation and tissue damage. The Panel concludes that the concentrations of Category I counterirritants used in external OTC anorectal preparations are safe and effective and will be discussed in greater detail in the individual ingredient statements.

The Panel concludes that there is no therapeutic rationale for using counterirritants intrarectally because there are no identifiable nerve fibers carrying the sensation of pain in rectal mucosa.

The primary mechanism of counterirritation is due to stimulation of nerve impulses. The skin response may be associated with a feeling of comfort, warmth, cooling, or tingling sensations (Refs. 1, 2, and 3). The afferent nerve impulses from the skin are relayed in the cerebrospinal axis to efferent vasomotor fibers supplying internal organs. Thus, the increased circulation to the skin has its counterpart in deeper integumental structures and in viscera innervated from the same segmental level of the central nervous system. Furthermore, when pain arises from an internal organ, sensory impulses simultaneously coming from the skin as a result of the action of an irritant either alter the character of the visceral sensations or, more probably, occupy the final common pathway to the partial or complete exclusion of the impulses arising from the viscera (Refs. 2 and 3). For example, a sore tooth may cause pain and swelling in the cheek by stimulation of the fifth cranial nerve (Ref. 2). The counterirritant is applied to the skin where pain is experienced, and this simple measure will often bring temporary relief (Ref. 2). The perception of other sensations from application of the counterirritant crowds out perception of the pain (Ref. 2).

It is the opinion of the Panel that the number and variety of subjective factors involving the perception of pain require the establishment of methodology for determining effectiveness of this group of drugs. This will require a subjective double-blinded method. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling, in Category I.)

Drugs are the least useful means available for producing counterirritation. Physical measures are employed much more frequently than are chemical agents. Heat is often an important measure, whether as a hot water bottle, heating pad, moist hot pack, or heat lamp (Ref. 3). The Panel concurs on the importance of heat in the relief of anorectal symptoms and recognizes the usefulness of sitz baths (soaking in warm water) as an ancillary measure.

Although no studies of this counterirritation phenomenon in the anorectal area were found, the Panel concludes that one ingredient, menthol

in aqueous solution, used in anorectal drug products does have this property to a sufficient extent to be useful externally for the temporary relief of pain, burning, and itching when used at the recommended dosages. (See part VI. paragraph B.1. below—Menthol in aqueous solution (external use).)

References

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B. Categorization of Data

1. *Category I conditions under which counterirritant ingredients are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I Active Ingredient

The Panel has classified the following counterirritant active ingredient as generally recognized as safe and effective and not misbranded:

Menthol in aqueous solution (external use). The Panel concludes that 0.25 to 1.0 percent menthol per dosage unit in aqueous solution is safe and effective for external use as a counterirritant in OTC anorectal preparations and not to exceed six applications per 24 hours.

(1) *Description.* Menthol is an alcohol obtained from members of the mint family, mainly *Mentha arvensis.* A synthetic form of menthol can be made from thymol and is composed of several stereoisomers varying in physical and toxicological properties. It is slightly soluble in water, very soluble in alcohol, chloroform, ether, glacial acetic acid, and mineral oil (Refs. 1 and 2).

(2) *Safety.* No studies relevant to safety of menthol for anorectal use were found, although absorption and toxicity after topical application of menthol have been reported. Radioactive menthol applied to dogs' chests did appear in the expired air in significant amounts (Ref. 3). Laryngospasm, dyspnea, and cyanosis resulted after fairly extensive topical application of 1 and 2.7 percent menthol ointments to the trunk and faces of two children (Ref. 4). Two deaths have also been reported from intranasal application of menthol ointments, although whether this represented inhalational toxicity or systemic absorption is not clear (Ref. 4).

Menthol is reportedly capable of irritating nasopharyngeal mucous membranes (Ref. 1), but concentrations and mechanisms for this effect are not clear. Menthol is frequently incorporated into cigarettes (1 to 2 mg/cigarette), suggesting a low toxicity. Menthol's ability to increase inflammation while giving symptomatic relief when used intranasally may be relevant to anorectal use (Ref. 1). Menthol is also capable of producing allergic manifestations, although only two reports have been found (Refs. 5 and 6). It is classified as a monocyclic terpene, and terpenes include many sensitizing agents occuring in plants and spices (Ref. 7). In view of the potential as a sensitizing agent and capacity to evoke allergic manifestation, the Panel recommends an appropriate warning. (See part VI. paragraph B.1. below—Category I Labeling.)

Although the relation between systemic absorption through skin or mucous membranes and absorption after oral ingestion is not known, toxicology for oral absorption will be used as a tentative guideline because toxicity by other routes is not quantified. A fatal oral dose of 2 g in human has been reported (Ref. 8). Ingestion of 50 to 500 mg/kg causes severe abdominal pain, nausea, vomiting, vertigo, ataxia, and coma (Ref. 9). Children are more sensitive to smaller doses (Ref. 1), but OTC anorectal ingredients are not recommended for children under 12 years of age. (See part II. paragraph O. above—Pediatric Dosage.)

The toxic level (2 g for adults) is far above the quantity of menthol used in marketed anorectal preparations. Consequently, the Panel concludes that menthol in aqueous solution is safe as a counterirritant for the temporary relief of pain or itching in concentrations of 0.25 percent to 2.0 percent, which is represented by 5 to 40 mg per dosage unit.

(3) *Effectiveness.* Menthol is absorbed through the skin and is widely used as a counterirritant by virtue of its ability to temporarily stimulate nerves for perception of coolness and depress those for pain (Refs. 1 and 10). It is effective locally in concentrations of 0.25 to 1 percent; although the literature reviewed use concentrations as little as 0.1 percent and as high as 3.5 percent, the data on safety and effectivenes support a more narrow range of 0.25 to 2 percent (Refs. 11 and 12). Because the same nerves carry the sensations of pain and itching, the relief of itching, noted in many clinical reports has been explained (Refs. 1, 10, 13, and 14). Pruritus due to histamine is not relieved either by menthol or any other commonly used antipruritic (Ref. 15). There is no proof, however, that histamine sensitivity is involved in the anorectal area; thus, it is reasonable that menthol is useful in the relief of itching.

The Panel has found no studies on menthol used alone in the anorectal area but concludes from effects and wide use on other areas of the body that menthol is effective externally as a counterirritant for the temporary relief of itching in the anorectal area.

(4) *Dosage.* Adult external dosage is 0.25 to 1.0 percent menthol per dosage unit in aqueous solution and not to exceed six applications per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for counterirritant active ingredients. (See part VI. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling:

(i) "May provide a cooling sensation."

(ii) "Temporarily relieves itching and soothes burning."

References

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(14) Anon., "Anesthetic Sprays and Wipes," *Medical Letter on Drugs and Therapeutics,* 11:70–71, 1969.
(15) Melton, F. M. and W. B. Shelley, "The Effect of Topical Antipruritic Therapy on Experimentally Induced Pruritus in Man," *Journal of Investigative Dermatology,* 15:325–332, 1950.

Category I Labeling

The Panel recommends the following Category I labeling for counterirritant active ingredients to be generally recognized as safe and effective and not misbranded.

a. *Indications.* (1) "For the temporary relief of itching or pain in the perianal area."

(2) "Can help distract from pain or itch."

(3) "Temporary relief of itch or pain in the perianal area."

b. *Warning: "Caution:* Certain persons can develop allergic reactions to ingredients in this product. If redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician."

2. *Category II conditions under which counterirritant ingredients are not generally recognized as safe and and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredients

The Panel has classified the following counterirritant active ingredients as not generally recognized as safe and effective or as misbranded:.

Camphor (external and intrarectal use)
Hydrastis (external and intrarectal use)
Methol (intrarectal use)
Turpentine oil, rectified (external and intrarectal use)

a. *Camphor (external and intrarectal use).* The Panel concludes that camphor is not safe and effective for external and intrarectal use as a counterirritant in OTC anorectal preparations.

(1) *Description.* Camphor is available as colorless crystals or crystalline mass obtained synthetically or naturally from *Cinnamonum camphora.* It volatilizes slowly, but has a pungent, aromatic taste and penetrating odor. Locally, it acts as a counterirritant producing a mild analgesic effect and a rubefacient effect. Systemically, it stimulates the central nervous system.

(2) *Safety.* Absorption of camphor through mucous membranes occurs rapidly and toxic levels may be reached in several minutes (Ref. 1). A major portion is quickly removed from the blood stream and conjugated by the liver into glucuronic acid after being oxidized to campherol or deposited in lipids where it is highly soluble (Ref. 2). Camphor poisoning, due to accidental ingestion, continues to cause morbidity and mortality, especially in children (Refs. 3, 4, and 5). Symptoms are caused by central nervous system stimulation, and death is due usually to subsequent respiratory failure. The probable lethal dose in humans is 50 to 500 mg/kg (Ref. 6).

Toxicity, when ingested, is well-supported by the literature (Refs. 1 through 11). Although there are no data to support toxicity associated with correct use, i.e., in concentrations of 1.6 to 7.0 percent in OTC preparations for anorectal disease, accidental ingestion continues to be a hazard. As noted recently by a physician, "One must ask whether products with tastes attractive to some children, used to soothe a baby's rash, decongest a nose, or treat a fever blister, should contain convulsive or a possibly fatal dose of a toxic compound in teaspoon quantities" (Refs. 5 and 8).

A recent report on two cases of camphor toxicity included a search of the literature in which 500 cases of camphor poisoning were reported in 1973 (Refs. 5 and 8). One submission to the Panel consisted of a letter that strongly recommended the elimination of camphor from the OTC market. This letter included reports of toxicity (Ref. 7).

Because camphor is absorbed so rapidly across mucous membranes, it is or can be highly toxic (Ref. 2); and, in view of its high lipid solubility and potential for storage in fatty tissues, the Panel concludes that it is not safe for use in OTC anorectal preparations.

(3) *Effectiveness.* Because camphor is effective as a counterirritant to relieve itch on other parts of the body, camphor has been used in medicine for centuries, first in China and subsequently in the western world (Refs. 2 and 3). The inclusion of camphor in OTC anorectal products is based on common usage over the centuries. Applied locally, camphor gives a sense of coolness when rubbed lightly and a sense of warmth with vigorous application. As a counterirritant, it relieves itch because of its effect on skin sensory nerves (Ref. 2). There are no controlled data available to support the effectiveness of camphor in anorectal disorders.

(4) *Evaluation.* When used correctly according to directions and in concentrations of 1.6 to 7.0 percent, there is no recorded evidence of significant morbidity and mortality. Yet the lethal dose is small; 50 to 500 (mg/kg) would probably cause death in a 150-pound man (Ref. 6). The effects of cumulative smaller quantities such as 7 percent of a 2-g dose applied six times daily would provide 840 mg of camphor daily. In view of the lipid solubility and consequent tendency to be deposited in adipose tissue, camphor presents an unacceptable hazard. There are not sufficient data to support the effectiveness of the use of camphor in anorectal disorders. Therefore, the Panel concludes that camphor can not be considered generally safe and effective for OTC anorectal products.

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b. *Hydrastis (external and intrarectal use).* The Panel concludes that hydrastis is not safe or effective for external or intrarectal use as a counterirritant in OTC anorectal preparations.

(1) *Description.* Hydrastis is also known as golden seal, yellow root, orange root, Indian Turmeric, eye root

and eye balm (Refs. 1 and 2). It consists of the dried rhizome and root of *Hydrastis canadensis*, which contains varying amounts of hydrastine alkaloids, berberine, and smaller amounts of canadine (Refs. 1 through 4).

(2) *Safety.* The pharmacological action of hydrastis is mainly due to hydrstine and to a lesser extent from berberine. One mL of a 5 percent solution produces strychnine-like convulsions on the intact frog (Ref. 4). The fluidextract administered parenterally to animals produced little or no effect, unless it was given intravenously when hypotension resulted (Ref. 4). Some doubt remains regarding its uterine action, but all reported results indicate that it produces depression of intestinal smooth muscle (Refs. 3 and 4).

Like hydrastis, the alkaloid hydrastine produces stimulation of the central nervous system when given in toxic doses (Ref. 4). Toxic doses causes exaggerated reflexes and strychnine-like convulsions, followed by paralysis and death from respiratory failure (Refs. 4 and 5). Evidence, though somewhat contradictory, suggests that its predominant action on the heart is that of a depressant. Like hydrastine probably produces depression of intestineal smooth muscle (Refs. 3 and 4). The Panel concludes that a 2-g dose of ointment currently containing this ingredient (Ref. 6) provides an unidentified quantity of hydrastis which makes it unsafe for OTC use.

Berberine, unlike hydrastine, has a depressant action on the central nervoud system, as manifested by respiratory depression (Ref. 7). Toxic doses depress the heart, relax blood vessels, depress respiration, and stimulate smooth muscle in the intestine, bronchi, and possibly the uterus (Ref. 3). It is also capable of producting local anesthesia with untoward side reactions (Ref. 8). Gleason et al. (Ref. 3) reports that there is a difference in opinion as to the toxicity of berberine and gives it a toxicity rating ranging from 2 (5 to 15 g/kg) to 5 (5 to 50 mg/kg). The Panel concludes that a 2-g dose of ointment currently containing this ingredient (Ref. 6) provides an unidentified quantity of berberine which makes it unsafe for OTC use.

No data regarding the safety of hydrastis after application to the anorectal area is available. Due to the possibility of absorption of some of the active constituents of hydrastis when applied to the anorectal area, the Panel concludes that hydrastis is not safe for use in OTC anorectal preparations.

(3) *Effectiveness.* Hydrastis was used by the Cherokee Indians both as a pigment and a medicine (Ref. 5). In medicine, the clinical use of hydrastis is based largely on empirical observations. It has few, if any, rational indications for use. The drug has been used as a bitter and stomachic, to check internal hemorrhage, and locally in catarrhal conditions, especially of the genitourinary tract. A survey of the early clinical literature reveals about 50 clinical conditions that were purportedly cured or benefited by hydrastis, hydrastine, or berberine (Ref. 4). Unfortunately, none of these are supported by definitive clinical data.

In his review of the literature published in 1950 pertaining to the pharmacology and therapeutics of hydrastis, Shideman (Ref. 4) noted:

(a) Hydrastis appears to have little effect on the central nervous system except in toxic doses, when it produces convulsive effects analogous to those of strychnine. (b) Parenteral administration of the fluidextract has little or no effect unless given intravenously, when hypotension results, probably because of a direct myocardial depressant effect of the drug. (c) Based on the data available, no conclusions may be drawn regarding its uterine activity, but all reports seem to indicate that it produces depression of intestinal smooth muscle.

A more recent review and a search of the current literature reveals no additional data or information supporting the clinical effectiveness of this drug in the treatment of anorectal disorders (Ref. 5).

The Panel concludes that hydrastis is not effective for use in OTC anorectal preparations because no clinical data supporting such use is available.

(4) *Evaluation.* On the basis of available evidence, the Panel concludes that hydrastis when used in anorectal preparations may be absorbed in sufficient amounts to produce toxicity. In medicine, the clinical use of hydrastis is based largely on empirical observations (Ref. 9). No clinical data supporting its use in anorectal preparations are available. The Panel regards claims as to its effectiveness as a counterirritant as irrational. Therefore, the Panel concludes that hydrastis is not safe or effective for OTC use in anorectal preparations as a counterirritant.

References

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c. *Menthol (intrarectal use).* The Panel concludes that menthol is safe but not effective for intrarectal use as a counterirritant in OTC anorectal preparations.

(1) *Description.* (See part VI. paragraph B.1. (1) above—Description.)

(2) *Safety.* If the intrarectal dose is considered to be equivalent to the oral dose, the fatal amount of natural menthol in man is approximately 1 g/kg (Ref. 1). This large amount greatly exceeds the amount delivered in preparations recommended for external use in which the Panel recommends a concentration of 0.25 to 1 percent menthol per dosage unit in aqueous solution. The Panel concludes that the concentration allowed for external use, therefore, would be safe for intrarectal use. (See part VI. paragraph B.1. (2) above—Safety.)

(3) *Effectiveness.* (See part VI. paragraph B.1. (3) above—Effectiveness.) There are no data to suggest effectiveness of menthol intrarectally. The action of counterirritants is dependent upon the presence of afferent nerves carrying pain sensations in the area to which the agent is applied. Because there are no such nerves in the rectum (rectal mucosa), counterirritants are ineffective in this area.

(4) *Evaluation.* The Panel concludes that menthol in concentrations of 0.25 to 1 percent per dosage unit in aqueous solution is safe but not effective for intrarectal use as a counterirritant because there are no pain sensory nerve fibers in rectal mucosa.

Reference

(1) "The United States Dispensatory," 27th Ed., Edited by Osol, A. and R. Pratt, J. B. Lippincott Co., Philadelphia, PA, pp. 697–698, 1973.

d. *Turpentine oil, rectified (external and intrarectal use).* The Panel concludes that turpentine oil, rectified, is not safe or effective as a

counterirritant in OTC anorectal preparations for external or intrarectal use.

(1) *Description.* Oil of turpentine is a volatile oil and is distilled from gum turpentine from species of *Pinus.* It is a thin, colorless liquid having a characteristic odor and taste, both of which intensify and become unpleasant with aging or exposure to air (Ref. 1). Soluble in oils and alcohol, it is insoluble in water (Ref. 1). It has been used as an expectorant and a stimulant; topically, it has been used as a counterirritant.

(2) *Safety.* Inhaled, it causes headache, confusion, respiratory and gastrointestinal distress (Ref. 2). After subcutaneous injection sterile abscesses result (Refs. 1 and 2). Contact with skin in sensitive individuals will cause erythema and itching (Ref. 2). Aspiration will cause chemical pneumonitis (Refs. 1 and 2). Intoxication is associated with pain, colic, nausea, vomiting, diarrhea, delirium, ataxia, and coma (Ref. 1). Painful urination and the abnormal presence of albumin and red blood cells in the urine are found with absorption of toxic doses (Refs. 1 and 2). Injury to the kidneys and to the gastrointestinal tract result from accidential ingestion (Ref. 2). It is readily absorbed from skin, lungs, and the gastrointestinal tract (Ref. 1). Ingestion of 15 mL in children and 150 mL in adults has caused fatal poisoning (Refs. 1 and 2). From information gathered, toxicity is high in accidental ingestion, use of increased amounts or concentration, and in aspiration and inhalation of vapor (Refs. 1 and 2).

3. *Effectiveness.* Turpentine oil, rectified, is used on the skin as a counterirritant. Review of the literature on this compound failed to demonstrate any support for use of this ingredient in the treatment of anorectal disease.

(4) *Evaluation.* The use of turpentine oil, rectified, on inflamed anorectal skin would cause futher destruction of tissue and increased symptoms. Therefore, the Panel concludes that there is no therapeutic rationale for the use of this ingredient in OTC preparations for anorectal disease and that such preparations should be removed from the market.

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Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of the counterirritant drug products are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel considers the following claim to be misleading and unsupported by scientific data.

"Promotes healing." This claim has no basis in connection with counterirritants.

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredient

The Panel concludes that the available data are insufficient to permit final classification of the below named counterirritant active ingredient. The Panel believes it reasonable to provide 2 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 2 years, however, the ingredient listed in this category should no longer be marketed in OTC products:

Juniper tar (external and intrarectal use). The Panel concludes that there is insufficient evidence to prove safety and effectiveness of juniper tar as a counterirritant for use in OTC anorectal preparations.

(1) *Description.* Juniper tar, also called oil of cade, is an oil obtained from the destructive distillation of the wood of *Juniperus oxycedrus.* The oil itself is a dark red, viscid, clear liquid with tar-like odor and warm bitter taste. It is composed of various quantities of the sesquiterpene cadinene, various hydrocarbons, phenol, acetic acid, cresol, and derivatives of pyrotechin, including guaiacol, although information on the relative quantities of these substances was not found. Juniper tar is slightly soluble in water and more soluble in ether (Refs. 1 through 5).

(2) *Safety.* No conclusion as to the actual safety of this heterogeneous mixture of materials could be made by the panel. The toxicity of phenol has been described elsewhere in this document and is pertinent because phenol is considered a representative ingredient of juniper tar. (See part IX. paragraph B.2.d. below—Phenol (external and intrarectal use).) Guaiacol (methylcatechol or methoxyphenol) has been given a toxicity rating of "very toxic" with a lethal does of 50 to 500 mg/kg by Gleason et al. (Ref. 5) and is described as slightly less corrosive and less toxic than phenol, but it is noted that percutaneous absorption is hazardous and skin irritation may result (Refs. 5, 6, and 7). Cresol, another constituent also related to phenol, has a spectrum and level of toxicity similar to phenol and guaiacol with the potential of producing local irritant and systemic effects if absorbed (Refs. 5, 6, and 7). The toxicity of other constituents is not known. Thus, the Panel was unable to judge the safety due to lack of information on the relative concentrations of these constituents as well as a lack of information on the safety of the clinical use of this substance.

(3) *Effectiveness.* The Panel concluded that, although by virtue of the presence of several constituents in juniper tar it could be effective as a counterirritant, lack of information as to the relative amounts of potentially useful constituents as well as any clinical information on effectiveness of the tar prevents any rational conclusion. Anecdotal reports and reviews suggest that it has been popular as an irritant for the treatment of various skin disorders, but no clinical data were found to support this (Refs. 1, 2, 5, and 8). Juniper tar has enjoyed long use as an irritant in the treatment of eczematous skin diseases and pruritus and concentrations from 1 to 5 percent (Ref. 2) and in higher concentrations for scalp treatment. It has also been used in the treatment of a variety of other ailments in ancient and present times in other countries (Ref. 8). Further, the decreasing demand for juniper tar may suggest its declining use. Because it is a mixture of substances, its effectiveness will vary with relative amounts of constituents. Therefore, further data on a standard mixture or isolation of the active components would be recommended for proof of effectiveness.

(4) *Proposed dosage.* Adult external and intrarectal dosage is 20 to 100 mg per dosage unit and not to exceed four applications per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for counterirritant active ingredients. (See part VI. paragraph B.1. above—Category I Labeling).

(6) *Evaluation.* Although widely used for centuries in the treatment of a variety of skin diseases, no reports of definitive clinical evaluation of juniper tar in anorectal diseases have been found.

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Category III Labeling

None.

C. Data Required for Evaluation

The Panel has agreed that the protocols recommended in this document for the studies required to bring a Category III drug into Category I are in keeping with the present state of the art and do not preclude the use of any advances or improved methodology in the future. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

VII. Astringents

A. General Discussion

Astringents are drugs that are applied to the skin or mucous membranes for a local and limited protein coagulant effect (Ref. 1). The word astringent is derived from the Latin "ad stringere" meaning "to draw firmly together."

When used in therapeutic doses or concentrations, astringents lessen mucus and other secretions and assist in the return to normal of local anorectal irritation and inflammation (Ref. 1). The limited coagulation (precipitation) of proteins protects the underlying tissue and produces a decrease in the volume of cells which is readily demonstrated by macroscopic or microscopic measurements (Ref. 1). A simple illustration of this effect is using an astringent as a mouthwash and noting the puckering effect upon the mucous membranes lining the cheeks (Ref. 1). However, the Panel concludes that the decrease in cell volume (implying a reduction in swelling) is not sufficient to warrant a labeling claim for reduction of swelling. (See part VII. paragraph B.2. below—Category II Labeling.)

Astringents are classified into two groups: (1) Mineral astringents, including heavy metals that combine with the albumin of the tissues and form insoluble precipitates, and (2) the vegetable astringents, such as tannic acid (Ref. 2).

Certain metallic ions, such as zinc, have the ability to precipitate protein and are primarily astringent; however, the astringent effects are considered in connection with its other pharmacological properties (Refs. 3 and 4). Metallic astringents are applied directly to inflammatory lesions of the skin or accessible mucous surfaces. The water insoluble substance, zinc oxide, has been used in a number of pastes and ointments or mixed with starch and kaolin and applied as a dusting powder or as calamine lotion (Ref. 1).

Astringents have a low cell penetrability; therefore, astringent action is essentially limited to the surface cells and interstitial spaces of skin and mucous membranes and is accompanied by contraction, wrinkling, and blanching of the tissue due to hardening of the capillary endothelium (Ref. 3). Mucus and/or other secretions may also be reduced, making the affected area drier (Ref. 5). These surface tissue changes, in the opinion of the Panel, can lead to a reduction of itching.

Although the relief of inflammation has been described, the Panel has found no convincing evidence that actual reduction of inflammation occurs following the application of astringents (Ref. 5). There is a theoretical possibility that the precipitation of surface proteins by astringents could increase inflammation. The mechanism of action of astringents cannot be accurately designated based on this concept, but the Panel recognizes the relief of the symptoms of burning, itching, discomfort, and irritation by astringents.

Some astringents have been used therapeutically to stop minor bleeding by precipitating proteins and by causing platelets to disintegrate and release thromboplastin, thus initiating the clotting mechanism (Ref. 6). The Panel concludes, however, that the potential seriousness of any type of anorectal bleeding does not warrant a labeling claim for control of bleeding. In fact, the Panel has recommended a warning on all anorectal products that anorectal bleeding be evaluated by a physician. (See part II. paragraph Q.5. above—Warnings.)

When astringents coagulate (precipitate) surface tissue protein, a thin layer is formed which can serve to protect underlying tissue. This precipitation can also aid in the removal of dead surface tissue from a wound area.

In summary, the Panel concludes that astringents used in the anorectal area provide an additional mechanism for the temporary relief of the symptoms of burning, itching, discomfort, and irritation.

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B. Categorization of Data

1. *Category I conditions under which astringent ingredients are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I Active Ingredients

The Panel has classified the following astringent active ingredients as generally recognized as safe and effective and not misbranded:

Calamine (external and intrarectal use)

Witch hazel water (external use)

Zinc oxide (external and intrarectal use)

a. *Calamine (external and intrarectal use).* The Panel concludes that 5 to 25 percent calamine per dosage unit (based on the zinc oxide content of calamine) is

safe and effective as an astringent in OTC anorectal preparations and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Calamine is a mixture containing not less than 98 percent zinc oxide and 0.5 percent ferrous oxide. The ferrous oxide is a pigment that provides color but is not an active drug. It is a pink, odorless, fine powder that is insoluble in water and nearly completely soluble in mineral acids (Refs. 1 through 3).

(2) *Safety.* The safety of calamine is the same as that of zinc oxide. (See part V. paragraph B.1.m. (2) above—Safety.) Therefore, the Panel concludes that calamine is safe as an astringent in OTC anorectal preparations for external and intrarectal use.

(3) *Effectiveness.* The effectiveness of calamine is the same as that of zinc oxide. (See part VII. paragraph B.1.c. (3) below—Effectiveness.) Therefore, the Panel concludes that calamine is effective as an astringent in OTC anorectal preparations for external and intrarectal use for the temporary relief of burning and itching.

(4) *Dosage.* Adult external and intrarectal dosage is 5 to 25 percent calamine per dosage unit (based on the zinc oxide content of calamine) and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for astringent active ingredients. (See part VII. paragraph B.1. below—Category I Labeling.)

References

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b. *Witch hazel water (external use).* The Panel concludes that 10 to 50 percent witch hazel water per dosage unit is safe and effective as an astringent for external application in OTC anorectal preparations and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Witch hazel water (hamamelis water) is prepared by macerating a weighed amount of recently cut and partially dried dormant twigs of *Hamamelis virginiana* for about 24 hours in about twice their weight of water; it is then distilled until no more than 850 mL of distillate is obtained from each 100 g. To each 850 mL distillate, 150 mL alcohol is added. Hamamelis water contains 14 to 15 percent alcohol. It is a clear, colorless liquid having a characteristic odor and taste and is neutral or acid to litmus paper (Ref. 1).

Hamamelis water has not been officially recognized in the standard pharmaceutical compendia since 1960 (Ref. 1). For example, hamamelis water may have alcohol added before or after the distillation process using different concentrations of alcohol (45 to 90 percent) (Ref. 2). It contains only a trace of oil (0.01 to 0.02 percent) (Ref. 3). the tannin of hamamelis bark on distillation remains in the residue and is absent from the distilled extract (Refs. 3 through 12).

(2) *Safety.* Aside from the slight stinging sensation, which has been attributed to the alcohol content (Refs. 9 and 13), no other reports of adverse effects to hamamelis water have been found in the available medical literature. However, because hamamelis water contains minute amounts of volatile oil, the possible occurrence of allergic contact dermatitis cannot be discounted (Refs. 3, 12, and 13).

The Panel concludes that hamamelis water can be used safely and that allergic reaction is rare, based on its long and extensive use.

(3) *Effectiveness.* Literature reports have attributed the astringent action of hamamelis water to its tannin content (Refs. 4, 8, 11, 14, and 15). However, it has been documented that no tannin comes over in the distillate (Refs. 10, 13, and 16). It is probable, but not documentd, that the astringent effect is due to the alcohol present in hamamelis water. Assumptions that its effectiveness is due to the small amount (0.01 to 0.02 percent) of volatile oil that has been found in hamamelis water have not been scientifically validated (Ref. 3). One study shows that hamamelis water shortens bleeding time and accelerates blood coagulation in rabbits (Ref. 3), which may be related to the astringency effects of hamamelis water.

The uses of hamamelis water reported in the literature have not been scientifically tested and are based on folklore (Refs. 13 and 17). Its popularity and use by consumers and the medical profession may be attributed to the trace amount of volatile oil which gives it a characteristically pleasant odor (Refs. 16 and 19). According to data submitted by a manufacturer (Ref. 20), hamamelis water is effective in the relief of itching, the discomfort of hemorrhoids, the relief of the symptoms of anorectal and perineal itch, and for postoperative care after hemorrhoidal surgery (Ref. 13). In one subjective study of 105 postpartum patients with episiotomy discomfort, 102 patients experienced a cooling sensation after the use of pads saturated with a solution containing 50 percent hamamelis water (Ref. 13). In the same study of 76 patients who reported itching, 70 of these patients obtained relief. Seventy-five of 81 patients who reporting burning obtained relief. In a similar study, 49 of 50 postpartum patients with episiotomies reported a cooling sensation; 35 of 38 patients reported relief of itching; and 39 of 43 patients reported relief of burning (Ref. 13). Therefore, the Panel concludes that hamamelis water provides temporary relief of itching and burning and is safe and effective for external application. No data have been presented to indicate that hamamelis water is of any value as an astringent for use in intrarectal application.

(4) *Dosage.* Adult external dosage is 10 to 50 percent witch hazel water per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for astringent active ingredients. (See part VII. paragraph B.1. below—Category I Labeling.)

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c. *Zinc oxide (external and intrarectal use).* The Panel concludes that 5 to 25 percent zinc oxide per dosage unit is safe and effective as an astringent in OTC anorectal preparations and not to exceed six applications per 24 hours or after each bowel movement.

(1) *Description.* Zinc oxide is one of a class of bertholide compounds where the ratio of zinc to oxygen is not exactly 1:1; a property that results in some chemical instabilities (Ref. 1). It is water insoluble, but it is soluble in weak acids, and in the presence of fats it tends to form other zinc compounds (Refs. 1, 2, and 3). It does no absorb water (Ref. 4). It is widely employed in a number of dermatologic conditions as an astringent and protectant and has been employed as a major ingredient of a basic ointment for incorporation of other drugs (Ref. 5).

(2) *Safety.* Zinc oxide has long been regarded as a relatively nontoxic substance when used either topically or orally (Refs. 5 and 6). Although the oxide is supposed to be inert and not absorbed (Ref. 4), it is not completely chemically stable so that free zinc or zinc ions may be available. However, no specific data are available.

Zinc is an essential trace metal and part of a normal diet in quantities of 10 to 15 mg daily (Refs. 7, 8, and 9). It is probable that even if moderate amounts are absorbed systemically zinc will not exert deleterious effects because there are suffficient metabolic mechanisms to cope with increased zinc on at least a short term basis (Ref. 9).

In amounts greater than 1 g, systemic zinc toxicity is manifested acutely by nausea, vomiting, lethargy, and severe pain (Ref. 6) and chronically by anemia and porotic bone changes (Ref. 10). Toxicity does not appear to relate to topical applications of zinc or zinc compounds except possibly, though unlikely, from very long-term use (Ref. 11). No reports of direct irritant or allergenic effects of zinc oxide were found.

(3) *Effectiveness.* Zinc oxide is widely used in an official preparation, zinc oxide paste, by dermatologists on acute lesions where there is a tendency to vesiculation, oozing, or crusting because the starch in this formulation absorbs excess moisture and secretions.

Zinc oxide is employed in many dermatologic conditions as an astringent. Its astringent properties are attributed to the ability of the salt to coagulate or precipitate proteins temporarily in the injured or inflamed area (Ref. 12). This provides a protective film, but also may promote healing by other mechanisms. This film cannot be formed on intact skin because free proteins are not present on the horny layer (Ref. 12), but the Panel recognizes that anorectal symptoms of burning and itch usually arise from injured or inflamed skin.

A study by Melton and Shelley (Ref. 13) compares the ability of 54 preparations to relieve itch produced on the forearm by the subcutaneous injection of histamine. The preparations containing zinc oxide did not relieve the itch nor did any of the other ingredients tested. However, the authors conclude that the data do not shed any light on the value of these agents in pruritus arising in skin showing abnormal permeability. Topical epinephrine by iontophroesis and in a penetrant ointment blocked the histamine-induced itching.

Zinc oxide is not generally used as a powder for direct application since it would not remain in contact with the affected area or skin. The usual concentration is 5 to 25 percent (Refs. 14 and 15) in some suitable vehicle to achieve adhesion to the site. The Panel concludes that based on the data reviewed, zinc oxide in a concentration of 5 to 25 percent is safe and effective as an astringent in anorectal preparations.

(4) *Dosage.* Adult external and intratectal dosage is 5 to 25 percent zinc oxide per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(5) *Labeling.* The Panel recommends the Category I labeling for astringent active ingredients. (See part VII. paragraph B.1. below—Category I Labeling.)

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Category I Labeling

The Panel recommends the following category I labeling for astringent active ingredients to be generally recognized as safe and effective and not misbranded.

a. *Indications.* (1) "Aids in protecting irritated anorectal areas."

(2) "Temporary relief of irritation."

(3) "Temporary relief of itching."

(4) "Temporary relief of burning."

(5) "Temporarily relieves itching and soothes burning."

(6) "Temporarilyy relieves discomfort."

b. *Warnings.* None.

2. *Category II conditions under which astringent ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredient

The Panel has classified the following astringent active ingredient as not generally recognized as safe and effective or as misbranded:

Tannic acid (external and intrarectal use). The Panel concludes that tannic acid is not safe or effective as an astringent in OTC anoretcal preparations.

(1) *Description.* Tannic acid is an amorphous powder with a glistening or spongy mass, soluble in water and alcohol, and almost insoluble in chloroform and ether. Natural tannic acid is usually obtained from nut galls that are formed by gall flies and that grow in oak trees.

(2) *Safety.* In 1942, Wells, Humphrey, and Coll (Ref. 1) were the first to report the relationship between absorption of tannic acid in appreciable amounts from large burned areas of the body and subsequent severe central lobular hepatic necrosis (destruction of central areas of liver segments). In 1963, McAlister et al. (Ref. 2) reported three fatalities in children from hepatic necrosis believed to be due to the use of tannic acid in barium enema examinations. In November of the same year five deaths were reported from acute liver failure following administration of barium enemas containing tannic acid (Ref. 3). The age range of these patients was 4 months to 79 years of age. The important pathologic findings were those manifesting severe parenchymal liver damage (Ref. 3).

Proponents for the use of tannic acid in the treatment of diarrhea and burns or continued use in barium enema examinations relied on the investigative studies that indicated insignificant levels of tannic acid in plasma after its use. It was only in the late 1960's that it was shown that the inability to detect significant levels of tannic acid in the plasma after its use was due to its rapid hydrolysis into gallic acid (Ref. 4).

Numerous animal studies have shown that tannic acid is toxic to liver (Refs. 5 through 8). Additional studies revealed injury to the kidney (Ref. 9). The route and duration of administration varied from subcutaneous to rectal, from 1 hour to 215 days (Refs. 5 and 6). A study by Korpassy and Kovacs (Ref. 6) confirmed cancer causing activity of tannic acid with subcutaneous administration but was unable to demonstrate liver changes with skin ulcers that were treated with tannic acid.

Several reports of allergic reaction in patients who became sensitized to tannic acid are found (Ref. 10), although this does not appear of as great a concern as the potential for liver and kidney damage.

therapeutically, tannic acid has been used from a 0.25 percent to 20 percent concentration. It is suggested that liver necrosis may be related to repeated topical applications of tannic acid by extrapolating from reports of liver necrosis in burn patients treated with tannic acid (Ref. 1). It is readily absorbed both through injured skin and mucous membranes and is not safe in the treatment of burns.

Unanimous agreement has not been reached concerning the use of tannic acid in barium enemas and in prebarium enema preparation (Refs. 2, 3, and 11 through 14). Tannic acid has been used as a precleansing enema and with barium sulfate as the ingredient of choice for diagnostic radiological study (Refs. 11 and 12). Tannic acid is believed to decrease mucous secretions by its astringent effect, to give greater mucosal detail by adhering to the bowel wall, to give better pre-X-ray cleansing and post-X-ray evacuation by its irritative effect on the bowel (Ref. 3). Equally effective ingredients for replacement of tannic acid have not been found (Refs. 3 and 15) but because of toxicity, most radiologists have stopped using tannic acid cleansing enemas and many have stopped using tannic acid with barium sulfate for diagnostic radiological study. Those who have continued to use it emphasize careful measurement and preparation to keep the concentration at 1.5 percent or less (Refs. 16 and 17).

(3) *Effectiveness.* Pharmacologically, tannic acid precipitates protein and forms insoluble complexes with many heavy metal ions, alkalies, and glycosides. It has little action on intact skin, but when applied to abraded tissue, it precipitates protein (tannate film) which serves as a mechanical protection (Ref. 18). On application to the mucosa of the gastrointestinal tract, it is said to exert the same protein precipitating effect, decreasing the transudate of fluids (Refs. 11, 12, 18, and 19) and secretions from the wall of the gastrointestinal tract (Ref. 18).

The astringent action of tannic acid on abraded or denuded skin and on mucous membranes has been well-documented (Refs. 11 and 12). Because of this characteristic, it has been used for the symptomatic treatment of diarrhea for years, especially in children (Refs. 18 and 20). Tannic acid was used extensively in the treatment of burns from 1925 to 1943 and was felt to be a protective mechanical barrier, preventing or decreasing the loss of fluids from the burned surface and protecting the burned area from infection (Ref. 18) until it became implicated in liver toxicity. Tannic acid in barium enemas is considered to be superior in dilineating early, significant mucosal changes (Ref. 11).

Tannic acid has been used in treating diarrheā and burns, and also in precleansing preparations; mixed with barium sulfate it is used in diagnostic X-ray studies (Ref. 9). It has been recommended for the treatment of acute anal and perianal inflammation, both as an irrigating fluid to clear out irritating substances and as an agent to slow down the continual drainage of the same irritated perianal skin. It has been used as a local application for protein precipitation to protect the irritated skin, providing a mechanical barrier (Refs. 18, 19, and 21).

This panel is concerned only with the review of the safety and effectiveness of tannic acid in OTC anorectal products. There are no data available to suggest or establish the value of tannic acid in the relief of anorectal symptoms. Therefore, the Panel finds that tannic acid is not effective.

(4) *Evaluation.* With the knowledge of its rapid absorption through inflamed skin and rectal mucosa as well as the knowledge of its hepatic and renal toxicity and its suspected carcinogenic properties, the Panel concludes that tannic acid is not safe or effective for use in OTC anorectal products.

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Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of astringent drugs are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel considers the following claim to be misleading and unsupported by scientific data.

"Reduction of swelling."

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* None.

VIII. Wound-Healing Agents

A. General Discussion

Several ingredients contained in OTC anorectal preparations are purported to have as their only apparent mode of action the acceleration of tissue repair or wound healing. In the following discussion, wound healing is used synonymously with tissue repair.

The primary lesions occurring in the anorectal area which potentially would be affected include hemorrhoids, fissures, and disruption of the protective epithelial surface. These disruptions may involve the epithelium, dermis, and other subcutaneous tissues. In the following discussion, inflamed hemorrhoids and hemorrhoidal tissue are considered as wounds, although the epithelium usually remains intact. The swelling that characterizes hemorrhoids and hemorrhoidal tissue is, in some instances, the result of the same inflammatory response involved in the wound-healing process that takes place anywhere in the body. Various factors will affect the rate of healing (Refs. 1 through 8) such as circulation of blood to the affected area, body position (i.e., erect vs. prone), the presence of disease and drugs. Schilling (Ref. 8) observed that it is more important to avoid complications and retardation of wound healing than to accelerate the normal rate of repair.

A claim for healing is currently associated with some anorectal OTC drug products. The Panel has studied the data submitted that are intended to support the claim for relief of anorectal symptoms as a result of wound-healing mechanisms and has concluded that these may account for the claimed therapeutic activity of the ingredients. However, insufficient work has been done to allow the Panel to conclude that ingredients in anorectal products classified as wound-healing (i.e., tissue repair) agents are generally recognized as safe and effective.

Wound healing is the process of returning an injured area to the condition where it is structurally sound and the surface is intact.

The process of wound healing can be divided into three general stages: (1) Cellular infiltration and inflammation; (2) a fibroblastic stage characterized by proliferation of collagen fibers (collagen synthesis) to form a matrix support for the wounds; (3) a maturation phase in which the collagen matrix is mechanically strengthened by formation of collagen cross-linkages (Refs. 1 and 2). Agents affecting wound healing act at one or more of these stages. Most agents promoting experimental wound healing, such as oxygen, ascorbic acid, and vitamin A appear to act primarily to promote collagen synthesis (Ref. 1).

Corticosteroids are used as antiinflammatory agents in various prescription drug products for anorectal disorders such as ulcerative proctitis to promote healing. The mechanism of action of steroids in ulcerative proctitis is complex and not completely understood. But conversely, steroids are known to retard surgical wound healing by inhibition of collagen synthesis in the second stage (Refs. 1 and 4). This inhibition can, in some cases, be reversed by administration of oral doses of vitamin A, which promotes collagen synthesis (Refs. 1, 4, and 8).

However, the effectiveness of OTC anorectal ingredients in clinical symptomatic relief and/or wound healing in anorectal disease has not been proved. No studies have yet conclusively correlated the use of wound-healing agents with anorectal symptom relief, although the Panel concludes that there is theorectical basis for such a relationship.

The pharmacologic category of wound healers is not one which is generally recognized as effective in the OTC market. The Panel is aware that work is currently in progress to study the effectiveness of wound-healing agents. But these agents have not found an established niche in any OTC drug preparations, nor have any such agents even been specifically recognized as useful in OTC treatment of anorectal disorders. When tested in accordance with part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I, wound-healing agents may be found effective and properly labeled for relieving anorectal symptoms. It is theoretically possible that such agents may prove to be effective for wound-healing when tested in accordance with part VIII. paragraph C. below—Data Required for Evaluation.

A claim for promoting healing of anorectal disorders or hemorrhoids has not previously been associated with ingredients in anorectal products that have been studied as wound-healing agents, e.g., live yeast cell derivative, vitamin A, vitamin D, shark liver oil, cod liver oil, peruvian balsam. One submission to the Panel did contain the label claim "promotes healing," but none of the ingredients have ever been classified as wound-healing agents and there are inadequate data to substantiate this claim.

The Panel recognizes that these wound-healing agents have no primary effect on pain, itching, burning, or swelling, but that relief of these

symptoms may follow as a secondary result of wound-healing, although there are insufficient data to establish the claim for relief of pain, burning, itching, or swelling (e.g., hemorrhoids).

However, the Panel further recognizes that, whatever their mechanism, these ingredients may provide symptomatic relief of discomfort of hemorrhoids. If wound-healing agent ingredients can be shown to be effective, by the subjective testing procedure outlined in an earlier section of this document, then they could make the Category I claim that they do relieve symptons of pain, itching, burning, or swelling. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

The Panel has adopted this dual approach because it recognizes that symptomatic relief is the therapeutic goal in OTC treatment of anorectal disorders, and that products that can prove subjective relief of symptons should be generally recognized as effective, even when the mechanism of action has not yet been conclusively elaborated.

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B. Categorization of Data

1. *Category I conditions under which wound-healing agent ingredients are generally recognized as safe and effective and are not misbranded.* None.

2. *Category II conditions under which wound-healing agent ingredients are not generally recognized as safe and effective or are misbranded.* None.

Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of wound-healing agent drug products are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel considers the following claims to be misleading and unsupported by scientific data.

a. "Helps shrink swelling of hemorrhoidal tissues caused by inflammation or infection."

b. "Starts right in to gently help reduce the swelling of hemorrhoidal tissues."

c. "Helps shrink swelling of hemorrhoidal tissues caused by inflammation and gives prompt temporary relief in many cases from pain and itching in tissues."

d. "Promptly relieves pain and itching for hours and actually helps shrink swollen inflamed tissues."

e. "Actually helps shrink the swelling of hemorrhoidal tissues caused by inflammation or infection."

f. "Lets skin heal itself."

g. "Actually helps shrink swollen inflamed tissues."

There is no generally recognized class of substances known as wound healing agents in the OTC market. Therefore, any claim that an ingredient is a wound-healing agent must be demonstrated by appropriate testing. (See part VIII. paragraph C. below—Data Required for Evaluation.)

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredients

The Panel concludes that the available data are insufficient to permit final classification of the following wound-healing agent active ingredients listed below. The Panel believes it is reasonable to provide 2 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed in OTC products.

The Panel has taken into account the fact that these products have been available for a number of years without claims for wound healing and without reports of serious health hazards. However because wound-healing agents are not ingredients generally recognized as existing in the OTC marketplace, the Panel has determined that testing must be quite stringent to prove effectiveness.

Cod liver oil (external and intrarectal use)

Live yeast cell derivative (external and intrarectal use)

Peruvian balsam (external and intrarectal use)

Shark liver oil (external and intrarectal use)

Vitamin A (external and intrarectal use)

Vitamin D (external and intrarectal use)

a. *Cod liver oil (external and intrarectal use).* The Panel concludes that there is insufficient evidence to prove safety and effectiveness of cod liver oil as a wound-healing agent for use in OTC anorectal preparations.

(1) *Description.* (See part V. paragraph B.l.d.(1) above—Description.)

(2) *Safety.* A review of the literature reveals no definitive data regarding the safety of cod liver oil as a wound healing agent in the treatment of anorectal disorders. (See part V. paragraph B.l.d.(2) above—Safety.)

(3) *Effectiveness.* The Panel concludes that claims regarding effectiveness of cod liver oil as a wound-healing agent in the treatment of anorectal disorders remain to be established. Several reports indicate that as a tissue stimulant cod liver oil does alter wound healing favorably (Refs. 1 through 9). Its successful clinical applicability as reported by numerous authors (Ref. 7) indicates that cod liver oil is a factor in promoting tissue repair, clinically and experimentally, but it is unclear whether this is due to its protectant or to its wound-healing effects.

Historically, cod liver oil was widely used clinically during the 1930's. Numerous clinical studies (Refs. 5, 7, and 9) were done, but generally were not double-blind controlled studies. Most of these studies were done prior to the era of antibiotic therapy, and the claimed salutary effects of cod liver oil need to be measured against the antibiotic treatment of wounds (Ref. 7).

In treating injuries of the anorectal area, the effects were not reduced in the presence of viable bacteria or other irritants (Ref. 7). Wounds of the mucous membrane reacted equally well. It is believed and reported by some investigators that increased transudation of leukocytes and fluid following application of cod liver oil medication indicates the presence of irritants that enlarge the vascular bed. Thus, excess fluid is released and there is lysis of necrotic tissue as well as decongestion. Moreover, although cod

liver oil dressings or ointments have been advocated to accelerate healing and reduce infection in burns, ulcers, and superficial wounds (Refs. 9 through 20), controlled observations have failed to substantiate claims of their superiority over other oily preparations used as protectants.

The Panel has concluded that a reasonable daily dosage for OTC anorectal products should not exceed the daily allowance of 10,000 IU vitamin A or 400 IU vitamin D.

(4) *Proposed dosage.* Adult external and intrarectal dosage is 200 mg per dosage unit and not to exceed 4.706 g per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for wound-healing agent active ingredients, pending testing for effectiveness. (See part VIII. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* Data to demonstrate effectiveness as a wound-healing agent will be required in accordance with the guidelines set forth below for testing would-healing agent ingredients. (See part VIII. paragraph C. below—Data Required for Evaluation.) In addition, data are required in accordance with the guidelines set forth in part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I in order to be classified as an anorectal active ingredient.

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b. *Live yeast cell derivative (external and intrarectal use).* The Panel concludes that there is insufficient evidence to prove safety and effectiveness of live yeast cell derivative as a wound-healing agent for use in OTC anorectal preparations.

(1) *Description.* Live yeast cell derivative (LYCD) is a very heterogeneous material of varying composition obtained by a series of extractions of the yeast *Saccharomyces cerevisiae*. Analysis of one batch of LYCD containing 3.6 million units/pound revealed the presence of pantothenic acid (2.5 mg/mL), pentose nucleic acid (7 mg/mL), nonglucose sugars and glutamic aspartic acid, alanine, and lysine (94, 11, 36, and 23 mg/mL, respectively) (Ref. 1). LYCD has a molecular weight of less than 5000 (Ref. 1). The origin of this analyzed batch is not clear, but according to literature supplied in one submission, this factor can be derived from yeast as well as other animal tissues (Refs. 2 through 6). The processes involve filtration of particulate cellular material from alcohol-treated, LYCD-containing filtrate. This filtrate may contain two separate activities, one stimulating respiration and another cell growth (Ref. 7), but it also stimulates the enzymes catalase and peroxidase (Ref. 8). LYCD in most instances will stimulate oxygen uptake in a variety of tissues (Refs. 9 and 10), but this effect is variable and not attributable to the pantothenic acid (Ref. 9). A unit of LYCD has been defined as the amount of LYCD as a dry solid which stimulates the oxygen uptake of 1 mg dry weight of rat abdominal skin by 1 percent (Ref. 11). The correlation between oxygen uptake and wound-healing potency has not been established.

(2) *Safety.* No studies of safety of LYCD have been specifically carried out, although no toxicity has been noted when the compound was used in experimental animals (Ref. 10) and no reports of clinical toxicity have been made or noted in the various clinical studies of the commercial product containing LYCD (Ref. 11). The Panel therefore assumes that the compound is safe for limited use (1 week or less), but does not have evidence for safety of long-term use beyond 7 days.

(3) *Effectiveness.* The effectiveness of LYCD in anorectal drug products in final formulation as submitted to the Panel has not been demonstrated in controlled or uncontrolled clinical trials. Of 4 studies (Ref. 11) reviewed by the Panel involving 416 patients, 2 studies (218 patients) were uncontrolled and single-blinded and the other two studies (198 patients) were double-blinded and uncontrolled but tested against a competitive product of unestablished effectiveness. In the latter studies there was no statistically significant difference between the ointments used. The competitive product also contains a wound-healing agent for which effectiveness has not been established. In addition, a minimum of 7 days was required before responses were to be evaluated by the investigators; this condition places the studies beyond the scope of OTC anorectal drug products. Suppositories containing LYCD showed a statistically significant difference over the competitive products but the same conditions prevailed as for the ointments tested in these studies. However, recent studies presented to the Panel suggest that this agent can promote the synthesis of collagen in vitro, as well as the healing of experimental rabbit ear wounds (Ref. 10). Further, because the rabbit ear wounds were contaminated and the wound healing was still greater than control, the Panel has concluded that these data suggest that LYCD could promote healing in the contaminated anorectal area. In various inflammatory

conditions of the anorectal area, the relevance of collagen synthesis is not established but may be involved in some aspects of recovery of the swollen tissue. Appropriate testing to confirm this relationship, when developed, will permit in vitro verification of effectiveness of any ingredient classified as a wound-healing agent.

The effectiveness of LYCD in a very small study (18 patients) utilizing donor wound sites in patients with burns suggests a method for testing and a potential wound-healing effect (Ref. 12). There is not sufficient evidence to show that LYCD temporarily shrinks swollen hemorrhoidal tissue. The Panel is aware through submitted data that 133.2 units LYCD per dosage unit is the concentration currently used in marketed products and recommends that this concentration be considered as the Panel's proposed dosage for LYCD.

(4) *Proposed dosage.* Adult external and intrarectal dosage is 133.2 units per dosage unit and not to exceed six applications per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for wound-healing agent active ingredients, pending testing for effectiveness. (See part VIII. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* LYCD in the concentration reviewed and proposed in this document does not require further safety testing. Effectiveness of LYCD in relieving anorectal symptoms such as burning, pain, itch, or swelling must be demonstrated. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations and Labeling in Category I.) Further, data to demonstrate effectiveness as a wound-healing agent are also required before claims as a wound-healing agent active ingredient can be made. (See part VIII. paragraph C. below—Data Required for Evaluation.)

(7) *Minority opinion proposing that LYCD be considered safe and effective as a wound-healing age.* The majority of the Panel have stated that live yeast cell derivative (LYCD) should be placed in Category III as a wound-healing agent. The minority opinion is reached that protectants and wound-healing agents should be grouped together under the pharmacologic category of wound-healing agents and that LYCD is safe and effective for OTC use.

The majority of the Panel have decided that LYCD is safe but should be in Category III because double-blind studies have not been made in the human anorectal area to prove that it is effective. The minority argues that the evidence produced in many experiments is far more important than any attempt at proof by double-blind studies.

Double-blind trials have been considered by the Panel as one method by which Category III ingredients can be elevated to Category I. However, there are several practical problems that make such a method very difficult and suggest that some other method should be available. These difficulties include the following considerations:

(i) What is the target population on whom the studies are to be done? Should it be composed of the patients who report to surgeons? Obviously such patients have the most severe diseases, many of which could not be expected to be helped by OTC preparations. Should the target population be from a hospital clinic? Here again the patients are likely to have relatively severe diseases because the costs of clinic care are high. The best target population should be composed of those individuals who come to a pharmacist or to an environment in which OTC drugs are sold because this group will include many individuals with anorectal symptoms that can be expected to respond most satisfactorily to OTC preparations.

The difficulties that accompany such a study are immediately apparent—placebo versus tested drug, a migrant population, lack of adequate follow-up, and possibly some medicolegal considerations make such studies difficult or even valueless, despite great effort.

(ii) The spectrum of anorectal diseases treated is so wide that any controlled clinical study will need an exceptionally large number of entries to prevent skewing of the results. For example, if the study group should happen to include a preponderance of patients with pruritus, the tested group should show unusually good results with essentially any application because most ingredients will relieve this symptom. On the other hand, if a large population of patients should have severe anal fissures, the results could be poor because many of these patients eventually will require surgical relief.

(iii) The normal rate of healing is difficult to define. Theoretically, it should be the time required for the relief of symptoms when no therapy other than cleanliness and warm baths are used. Yet it is hard to find an individual who will refuse to apply in addition a soothing ointment in the presence of troubling symptoms.

(iv) Vehicles used in testing in comparison with any active drug usually are protectants and by themselves will allay symptoms. Thus lanolin, petrolatum, zinc oxide, or cocoa butter can be expected to produce relief in a high percentage of patients from symptoms of pruritus and irritation. The effect of the addition of another active ingredient may be extremely difficult to determine in patients in double-blind studies that rely on symptomatic relief; meanwhile, clear proof of the effectiveness of such an active agent could be obtained by other methods.

(v) Adequate models that furnish closely comparable lesions in different patients are essential if double-blind studies are to be done. To procure them is more difficult. Postoperative hemorrhoidectomy patients or patients with episiotomies could serve but it should be noted that their wounds are deeper and more serious than most wounds that are treated by OTC preparations. Comparable lesions of which the only symptoms are subjective can be judged only by subjective responses. It would be far more scientific to use data that can be obtained by observation by independent investigators and that can be quantitated.

(vi) Patients vary widely in their responses to treatment, depending upon individual differences and also upon the health of the individual at the time that the test is made. It therefore is best to test ingredients with and without vehicles in the same patient at the same time. Such tests in the perianal area at the same time are impossible because one combination placed on one side of the anus necessarily will be mixed rather freely with another placed on the opposite side. Hence, double-blind studies that may appear to be feasible may actually introduce many practical difficulties. It therefore seems reasonable to include a second method by which effectiveness can be judged.

This second method can be described as follows. If an ingredient is proved safe and can be proved to be effective in ex vivo tests, in tests on animals, and in areas of the human body other than the anorectum, it can be accepted as an effective agent. Tests of safety of ingredients rely heavily on such data from animals or other methods of administration of drugs, and it seems only logical that effectiveness should be judged in the same way.

It is proposed that, on this basis, LYCD together with protectants can be classed as wound-healing agents.

Effectiveness can be determined in general either by the relief of symptoms or by healing of the underlying disease. Relief of symptoms may be obtained without healing (e.g. as after application of a local anesthetic to abraded skin) but healing of any underlying disease necessarily will be accompanied by

relief of symptoms. An all-inclusive name to describe the diseases of the rectum that have been listed above may be "lesions" or the popular term "wounds."

Thus, healing of anorectal wounds could be measured by sustained symptomatic relief, in contrast to, for example, temporary relief afforded by local anesthetics or counterirritants. Wound healing, however, is much more complex and can be investigated in many ways that are far more scientific.

Normal healing should be defined as that which occurs under natural circumstances without the application of any type of protection or medication. Experience with wounds in all parts of the body has led to the clinical observation that protective materials hasten healing. The application of a plastic covering or the application of ointments that contain protectants and prevent water loss from the skin have proved effective because they permit healing to occur more rapidly than occurs when a wound is untreated (Ref. 13). Skin grafts from the same individual, from cadavers, or from pigs are used widely in the treatment of wounds due to burns (Ref. 14).

Obviously, there must be a quantitative variation in the speed in which these various agents act. Goodson et al. (Ref. 15) have shown that in the rabbit's ear open wounds heal more rapidly after application of LYCD than after application of petrolatum. That some agents are considered to be more powerful than others have been considered by the Panel, and the pharmacologic group of wound-healing agents was suggested; this designation signified a contribution to wound healing that is much more rapid than occurs with a bland protectant such as petrolatum.

Anorectal tissues in diseased states usually manifest either irritation or varying degrees of inflammation. Irritated skin either has lost its superficial layers of keratin or demonstrates cracks that extend through the corium which consists of dense, vascular connective tissue. These changes are dependent upon water loss, which in turn depends chiefly on a thin layer of epithelial cells near the base of the stratum corneum (Ref. 16). Mild degrees of dryness of the skin lead to scaling, and severe dryness to fissures, inflammation, and dilation of subcutaneous vessels (Ref. 16).

Increased water loss from skin therefore can lead to irritation and inflammation and reduced loss to healing. The water loss from normal skin of the human forearm has been compared with that of skin to which various protectants have been added. Thus, the application of petrolatum led to an average reduction of moisture loss of 48 percent, lanolin to a reduced loss of 32 percent, and mineral oil to a reduced loss of 28 percent (Ref. 17).

The difference in the rate of healing of wounds by the application of various agents has not been studied sufficiently to justify a sharp distinction of protectants and wound-healing agents. In the opinion of the miniority group of the Panel they should be placed together in the pharmacologic group of wound-healing agents.

Despite the observations that wound-healing agents such as protectants have been effective, laboratory studies or quantitative comparisons of various agents until recently have been essentially undeveloped. However, it is now possible to accept evidence from much more conclusive studies that have been done in animals, human skin, and excised anorectal tissues that prove the effectiveness of LYCD, rather than simply to rely on the old clinical dictum of relief of symptoms of itching, burning, pain, or irritation, for which all wound-healing agents could qualify.

These recently developed methods have included the following: (a) Evidence that oxygen uptake of tissues is increased by LYCD. Oxygen supply increases healing due to increased differentiation of fibroblasts and increases collagen synthesis. LYCD has been shown to stimulate oxygen consumption of rat skin, human skin, human fibroblasts, rabbit fibroblasts, and human leukocytes (Ref. 18).

The product tested contains 1 percent LYCD, 3 percent shark liver oil, an ointment base of petrolatum, and phenylmercuric nitrate as a preservative. The oxygen uptake of shaved rat skin when incubated with the product with and without LYCD has been determined (Ref. 19). Increased oxygen uptake occurred with the LYCD.

(b) Collagen synthesis is increased by LYCD. In vivo studies of human skin showed an increased rate of conversion of proline to hydroxyproline in the presence of LYCD (Ref. 18). It is known that one of the major components of the healing process of any wound is accumulation of collagen (Ref. 20), and that the formation of hydroxyproline is a measure of collagen synthesis (Ref. 18).

(c) Using wound chambers that were placed in rabbit skin, LYCD increased the accumulation of tissue within these chambers compared with the tissue in the chambers of the controls. This is accepted as another measure of wound healing (Ref. 18).

(d) Specimen of perianal tissue were excised and tested in vitro to determine the rate of conversion of proline to hydroxyproline, or in other words, the rapidity of the formation of collagen. In three experiments comprising anoderm and perianal tissues and rectal mucosa and submucosa, LYCD increased the collagen synthesis by 82.5 percent (Ref. 21).

(e) Evidence that healing of wounds made on rabbit's ears is more rapid after application of LYCD than after application of petrolatum (Ref. 15).

(f) Evidence in preliminary experiments in a few patients indicated that application of LYCD to one of two paired skin donor sites in humans led to more rapid healing than when the vehicle alone was applied (Ref. 22).

Use of paired donor sites that are to be used when skin grafts are taken furnishes an excellent method that can be carefully controlled because two wounds of uniform depth and size in the same patient can be studied simultaneously. Such a method is capable of wide use in determination of the effectiveness of many ingredients.

(vii) The minority opinion concludes that these sophisticated experiments are much more definitive than attempts to carry out double-blind studies on patients with perianal compliants. Such important observations should not be discarded simply because they have not been done in the perianal area. They are much more conclusive than the alternative method which would require essentially subjective responses to the complaints of itching, irritation, and pain.

It would seem appropriate to include protectants as wound-healing agents. For this pharacologic group, temporary relief of the symptoms of itching, irritation, or pain can be accepted as Category I claims. It is the conclusion of the minority of the Panel that LYCD should be placed together with the Category I protectants in the pharmacologic group of wound-healing agents as safe and effective.

However, if a claim is to be made that certain ingredients are far superior to others and a claim for more rapid healing is made, this will require testing in comparison with all other ingredients in the pharmacologic group of protectants before such claims could be established; the methods cited above within this discussion could be used as models.

(viii) *Labeling*—(*a*) *Category I labeling.* "For the temporary relief of itching, pain, burning, or irritation in the perianal area."

(*b*) *Category II labeling.* (*1*) "Shrinks hemorrhoids."

(*2*) "Promotes more rapid healing than other products."

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c. *Peruvian balsam (external and intrarectal use).* The Panel concludes that Peruvian balsam is safe for use as a wound-healing agent, but there is insufficient evidence to prove effectiveness for use in OTC anorectal preparations.

(1) *Description.* Peruvian balsam, also called Indian balsam, China oil, and Honduras or Surinam balsam, is a complex mixture consisting of approximately 25 to 50 percent of an oleoresin and from 50 to 65 percent of a volatile oil that is composed of the esters of benzoic and cinnamic acids, as well as vanillin, benzyl banzoate, benzyl cinnamate, nerolidol, farnesol, small amounts of coumarin, and benzyl alcohol (Refs. 1 and 2). It is obtained from the tree *Myroxylon pereirae*, a member of the *P. leguminosae* family that is native to Central America (Refs. 3 and 4).

(2) *Safety.* The Panel concludes, based on quantities used in submitted data, that Peruvian balsam is safe in concentrations of from 1 to 3 percent (Ref. 5) but notes that it can produce significant skin irritation in higher doses and can also produce allergic skin reactions. This agent has been defined as moderately toxic (toxic dose equals 0.5 to 5 g/kg), but it has been ingested and even injected intravenously without acute ill effects (Ref. 6). Taken orally, up to 50 g of benzoic acid, one of its major constituents, will result in only gastric distress (Ref. 7). In humans, cinnamic acid is largely excreted in the urine as benzoic and hippuric acids (Ref. 6).

Volatile oils are irritating to most tissues (Ref. 7). One study of dermatologic preparations on rabbit skin showed 15 percent Peruvian balsam gave irritation, but 10 percent and 5 percent did not; however, all three showed erythema when combined with X-radiation (Ref. 8).

In contrast, there are several reports attesting to the allergenicity of Peruvian balsam, the incidence ranging from 10 to 20 percent in tested patients (Refs. 9 through 12), with a relatively higher incidence in children (Ref. 9). The fractions or the components of the mixture which have caused the allergenicity have not been identified.

(3) *Effectiveness.* The effectiveness of Peruvian balsam as a wound-healing agent has not been established. When incorporated in an ointment base, it has been used to treat indolent ulcers by theoretically stimulating cell proliferation (Ref. 13). The dosage usually employed is 10 percent in an ointment and approximately 3 percent or less in suppositories (Refs. 13, 14, and 15). There are no available studies proving its effectiveness as a wound-healing agent in anorectal disorders. Although the study by Bloom and Lorincz (Ref. 13), which reported healing of chronic lesions after addition of Peruvian balsam and demonstrated an in vitro antibiotic effect, was suggestive, it falls short of any clear interpretation as to the effectiveness of the agent. Other analogous studies were not found, with the exception of one that also reported beneficial effects on skin lesions, but other potential active ingredients were used together with Peruvian balsam (Ref. 16). Because Peruvian balsam varies in its content (Ref. 1), it is conceivable that any demonstrable effectiveness may vary. Effectiveness would seem to be best determined by identification and examination of the individual components.

(4) *Proposed dosage.* Adult external and intrarectal dosage is 20 to 60 mg per dosage unit and not to exceed 360 mg per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for wound-healing agent active ingredients pending testing for effectiveness. (See part VIII. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* Peruvian balsam in the concentration reviewed and proposed in this document does not require further safety testing. Effectiveness of Peruvian balsam in relieving anorectal symptoms such as burning, pain, itch, or swelling must be demonstrated. (See part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.) Further, data to demonstrate effectiveness as a wound-healing agent are required before this ingredient is labeled as a wound-healing agent in anorectal products. (See part VIII. paragraph C. below—Data Required for Evaluation.)

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d. *Shark liver oil (external and intrarectal use).* The Panel concludes that there is insufficient evidence to prove effectiveness of shark liver oil as a wound-healing agent for use in OTC anorectal preparations when used at the recommended dosage.

(1) *Description.* (See part V, paragraph B.1.j.(1) above—Description.)

(2) *Safety.* Corroborative data establishing the safety of shark liver oil as a wound-healing agent in anorectal preparations is not available. Vitamin A, a normal constituent of shark liver oil, in excess would be harmful, producing a connective tissue resorption syndrome (Ref. 1). However, the Panel found in the data submitted for review that the quantity of vitamin A present (Ref. 2), is sufficiently low (1,710 International Units/gram of product) when the shark liver oil is limited to 3 percent and does not present a hazard to the consumer when used according to the recommended dosage. (See part VIII. paragraph B.3.e.(2) below—Safety.) The safety of vitamin D found in shark liver oil in the concentration used in the data submitted lacks verification when used in the external treatment of anorectal disorders. The Panel finds in the data reviewed that the quantity of vitamin D present in the product containing 3 pecent, by weight of shark liver oil, (Ref. 2) is 2.25 IU/g of product and does not present a hazard to the consumer when used according to the recommended dosage. (See part VIII. paragraph B.3.f.(2) below—Safety.)

(3) *Effectiveness.* The effectiveness of shark liver oil as a wound-healing agent in anorectal preparations has not been confirmed by definitive clinical data (Ref. 1). While some wound healing might be attrubuted to the vitamin A content of shark liver oil, there are not definitive data to support this claim (Ref. 3). Likewise, the effect of vitamin D on soft tissued wounds has not been described but is said to be important in states of rickets, vitamin D deficiency, and abnormal calcium balances (See part VIII. pargraph B.3.e.(3) below—Effectiveness and part VIII. paragraph B.3.f.(3) below—Effectiveness.)

(4) *Proposed dosage.* Adult external and intrarectal dosage is 60 mg per dosage unit and not to exceed 240 mg per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for wound-healing agent active ingredients, pending testing for effectiveness. (See part VIII. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* Data demonstrating the safety and effectiveness of shark liver oil as a wound-healing agent will be required. (See part VIII. paragraph C. below—Data Required for Evaluation.)

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(3) Minutes of the OTC Panel on Hemorrhoidal Drug Products, 14th meeting, May 1, 2, and 3, 1975.

e. *Vitamin A (external and intrarectal use).* The Panel concludes that there is insufficient evidence to prove effectiveness of vitamin A as a wound-healing agent for use in OTC anorectal preparations at the recommended dosage.

(1) *Description.* Vitamin A is a suitable form of retinol or vitamin A alcohol. It may consist of retinol or esters of retinol formed from edible fatty acids, principally acetic and palmitic acids. Retinol is a light yellow to red, oily liquid and is unstable in air and light. Pure vitamin A alocohol occurs as yellow prisms or as yellow crystalline esters of acetic and palmitic acids. All naturally occurring forms are water insoluble. Another representative of vitamin A occurring in nature is vitamin A–2. It has only about one-third the biologic activity of vitamin A–1. and has no commercial significance. Commercial preparations of vitamin A are for the most part synthetic retinol esters and have largely replaced natural vitamin A from fish liver oils. Preparations available range from solutions of pure synthetic vitamin A in oil to numerous fish liver oils and concentrates that contain both vitamin A and vitamin D in various proportions. One IU vitamin A is the specific biologic activity of 0.3 μg of the all-trans isomer of retinol (Refs. 1 through 4). The Panel knows of no studies regarding the degree and extent of absorption of vitamin A through the skin or mucous membranes, factors which would influence both it safety and effectiveness.

(2) *Safety.* The acute toxic dose of vitamin A in the adult is in the range of 2,000,000 to 5,000,000 IU. In the infant, the ingestion of doses as low as 75,000 to 300,000 IU can precipitate acute toxic signs (Ref. 5). Hypervitaminosis occurs both in young children and adults receiving more than 100,000 IU vitamin A daily over several months Ref. 6). There is no evidence to indicate that the oral administration of 10,000 IU vitamin A daily is toxic for any age group.

The Panel knows of no clinical evidence to indicate that external application of vitamin A to the skin or mucous membranes is safe. Absorption of vitamin A through the skin when applied in the form of cod liver oil in infants and in rats has been reported (Ref. 7). Similar absorption from the anorectal area may be presumed to occur, and clinical data regarding degree and extent of absorption are needed to evalutate its safety if an OTC anorectal drug product contains more than 1,710 IU/g, which is the level of currently marketed anorectal drug products. When used at the recommended dosage, this level does not present a hazard to the consumer.

(3) *Effectiveness.* The Panel concludes that vitamin A has an effect on wound-healing as demonstrated by in vitro tests and studies in animals. The Panel makes this conclusion on the basis that the effectiveness of vitamin A in promoting experimental wound-healing is apparently due to its ability to promote collagen synthesis (Refs. 8 and 9). This phenomenon has been demonstrated in a number of well-controlled animal experiments (Refs. 10 through 19). However, the Panel wishes to point out that the clinical effectiveness in the anorectal area remains to be demonstrated in clinical trials of vitamin A as a wound-healing agent in various applications of concentration and dosage interval not to exceed the maximum dose of 10,000 IU (3.44 mg) per 24 hours.

The label for a vitamin A preparation must give the form, source (synthetic or natural), and amount of vitamin A per dosage unit, and the recommended daily dosage.

(4) *Proposed dosage.* Adult external and intrarectal dosage is 1,710 IU (0.5 mg) per dosage unit and not to exceed 10,000 IU (3.44 mg) per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for wound-healing agent active ingredients, pending testing for

effectiveness. (See part VIII. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* When present at the recommended dosage, vitamin A is safe for use in anorectal OTC products. The effectiveness of vitamin A as a wound-healing agent for use in OTC anorectal preparations has not been established. While its wound-healing ability has been demonstrated in animal experiments, no data confirming its effectiveness in the human anorectal area is available. The Panel recommends double-blind clinically significant studies to establish the effectiveness of vitamin A as a wound-healing agent in OTC anorectal preparations. (See part VIII. paragraph C. below—Data Required for Evaluation.)

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f. *Vitamin D preparations (ergocalciferol and cholecalciferol) (external and intrarectal use).* The Panel concludes that Vitamin D preparations are safe for use at the recommended dosage but that there is insufficient evidence to prove effectiveness of vitamin D preparations as wound-healing agents for use in OTC anorectal preparations.

(1) *Description.* Two forms of vitamin D are recognized officially—ergocalciferol (vitamin D–2) and cholecalciferol (vitamin D–3). Ergocalciferol and cholecalciferol occur as white, odorless crystals that are soluble in fats and in fat solvents such as ether, alcohol, or chloroform, but insoluble in water. Both forms are stable over long periods of time in oil solution but are quite unstable in the presence of mineral salts. The activity of the two substances is commonly assumed to be equivalent. One mg of each of these vitamins represents 40,000 IU. Because they are assumed to be equivalent, the collective term, vitamin D, will be used in the following discussion (Refs. 1, 2, and 3).

(2) *Safety.* A search of the literature reveals no definitive data regarding the safety of vitamin D as a wound-healing agent in the treatment of anorectal conditions. The Panel wishes to point out that vitamin D has a serious toxic potential. In large doses of 1,000 to 3,000 IU/kg daily of body weight, vitamin D may produce tetany, acute pancreatitis, convulsions, and pitressin resistant diabetes insipidus; death has resulted both in experimental animals and in man due to renal insufficiency (refs. 4 and 5). A high calcium diet potentiates the toxic effect of vitamin D (Refs. 4 and 5). In infants as little as 1,800 IU daily may lead to possible growth inhibition (Ref. 6). Some persons who are apparently hypersensitive to vitamin D may suffer harmful effects even from low doses. Excessive intake of vitamin D during pregnancy may produce in infants a nonfamilial, congenital, supravalvular aortic stenosis, often in association with other signs of hypercalcemia (Ref. 5). Unfortunately, while there is substantial evidence regarding the toxicity of vitamin D when administered orally in large doses (Ref. 7), there are no similar data regarding its external use in the treatment of anorectal disorders. The studies reported in the literature have dealt with vitamin D as one component of a mixture (Ref. 8). While definitive data regarding the topical absorption of vitamin D are not available, such a possibility cannot be discounted. Thus, it is possible that the amount of vitamin D absorbed following topical application when added to that normally provided by diet (e.g., fortified food or beverages) (Ref. 9) or other sources (e.g., oral vitamin D medication) may be sufficient to result in manifestations of vitamin D toxicity. Furthermore, since the body stores vitamin D, the cumulative effects must also be considered. However, the Panel concludes that vitamin D when used in anorectal drug products at the recommended dosage is safe.

(3) *Effectiveness.* The Panel concludes that the effectiveness of vitamin D as a wound-healing agent in treating anorectal disorders has not been corroborated by controlled clinical trials. Liteature reports deal with vitamin D as a component of a mixture. These studies fail to prove conclusively that positive results, particularly in wound healing, can be attributed to the vitamin D content in the preparations used. Its effectiveness in wound healing has been challenged on the grounds that it is ineffective unless bone is involved or there is a vitamin D deficiency. Preparations like shark liver oil and cod liver oil which contain vitamins A and D have a protectant effect that is attributed to their oily nature (Refs. 10 through 15). No definitive clinical data supporting wound-healing effect in these oils as being due to their vitamins A and D content are available. According to data presented to the Panel, no one has ever shown that vitamin D has any effect on soft tissue wounds. There is no satisfactory evidence to indicate benefits from inclusion of vitamin D in preparations for topical use (Ref. 17).

(4) *Proposed dosage.* Adult external and intrarectal dosage is 4.5 IU (0.00011 mg) per dosage unit and not to exceed 27 IU (0.00066 mg) per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for wound-healing agent active ingredients. (See part VIII. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* There are insufficient definitive clinical data establishing the effectiveness of vitamin D at the recommended dosage as a wound-healing agent in the anorectal area and further testing is to be carried out. (See part VIII. paragraph C. below—Data Required for Evaluation.)

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Category III Labeling

The Panel concludes that the available data are insufficient to permit final classification of the claims listed below.

Additional data are required to support the following wound-healing agent claims:

a. "May promote healing of injured or irritated skin or mucous membrane."

b. "May help promote tissue repair in the anorectal area."

c. "For the relief of minor irritations in the anorectal area."

d. "Temporarily shrinks swelling of hemorrhoidal tissue caused by inflammation."

C. Data Required for Evaluation

The Panel has agreed that the protocols recommended in the document for the studies required to bring Category III wound-healing agents into Category I are in keeping with the present state of the art and do not preclude the use of any advances or improvements in methodology in the future.

It should be noted that all OTC anorectal products are primarily used for the relief of symptoms associated with anorectal disorders. Therefore, any ingredient must be shown, in clinical double-blind studies, to be able to relieve one or more of the common symptoms of itch, burning, pain, discomfort, or swelling to a statistically significant degree over control. This requirement is true whether the mechanism is known or not because the mechanism of providing relief is often much more difficult to determine; a study to determine mechanism may not always directly relate to clinical symptomatic relief. In some cases, experiments may demonstrate both symptomatic relief and a mechanism such as healing.

To make a claim as a wound-healing agent, it not only must be demonstrated that such an agent provides symptomatic relief of anorectal symptoms but also that it has the capacity to promote wound healing as shown in clinical testing in the anorectal area as described within this section. (See also part II. paragraph L. above—Criteria and Testing Guidelines for Placing Category III Ingredients, Combinations, and Labeling in Category I.)

1. *Principles in the design of an experimental protocol for testing wound-healing agents*—a. *General principles.* Because of the unique nature of the contaminated and traumatized (by bowel movement, toilet tissue, and sometimes clothing) anorectal area, anorectal agents for which the claim of wound healing is desired should ideally be tested in the anorectal area in humans. Ancillary information suggesting a wound-healing action of other sites is helpful, e.g., collagen synthesis, but would only constitute evidence of activity in the anorectal area if it otherwise corresponds to the demonstrated clinical relief of symptoms. For example, if wound healing requires 14 days and symptomatic relief is obtained in one application, another mechanism must be assumed to be operating and any claim for wound healing is not appropriate.

Two kinds of studies can be developed to demonstrate wound healing. Those done in the anorectal area are called anorectal wound-healing studies, and those done elsewhere on the body are referred to as other clinical wound-healing studies. Those studies carried out in the anorectal area can be designed to test symptomatic relief also, although this might require special precautions to prevent bias.

All studies must be carried out with a 7-day end point to make these studies relevant to OTC use. It is conceivable that some agents may be effective over longer periods or require a longer period of time to demonstrate effectiveness, i.e., more than 7 days, but because OTC use primarily involves symptomatic problems, all prolonged effectiveness claims must be approved through the new drug application process and marketed as prescription drugs.

b. *Selection of patients*—(1) *Anorectal wound healing.* Patients with anorectal disease of a nature that allows quantitation by biopsy, photography, or other studies.

(2) *Other clinical wound-healing studies.* Other studies of wound healing may be done in normal human volunteers or in patients with other relatively defined standard wounds such as skin graft, punch biopsies, or the like. These must be, likewise, quantifiable by measurement, photography, or other quantitative methods, and/or clinical grading system.

c. *Methods of study.* The minumum number of visits should be the initial visit and a followup in not more than 7 days.

(1) *Anorectal wound healing.* Because of the extreme variability and difficulty with study in this area, double-blind studies are needed despite the difficulties involved. Studies should be directed specifically to either external or intrarectal use. Patients will be selected at random manner with sequential

statistical analysis to minimize the number of patients needed. The major criterion for selection of patients is the presence of a lesion that has a potential of healing and that is amenable to consistent quantification. More than one method of quantification may be used but must be consistently used in all comparative studies. Certain methods can be suggested and other methods may be acceptable and can be developed in conjunction with the Food and Drug Administration (FDA). For example, use of a fixed focus camera with standardized lighting can allow clinical grading and measurement of lesion. A clinical grading system is also acceptable in a double-blinded study. In some cases biopsy of skin areas may be feasible, although this is less acceptable due to hazards involved and, more importantly, due to the extreme variability possible because of pathological variations of a given wound site. Certain other measurements of epithelization and wound healing, such as use of dyes or degree of blood flow, may be also shown to be useful. These studies can be correlated with clinical symptomatic improvement by patient questionnaires. However, to prevent bias, methods of data collection that prevent communication of results between patient and doctor should be considered. Such communication has certain undesirable features. If the physician is receiving a fee for service from the patient, the patient will not appreciate any barrier in the way of service for which he is paying. Thus, it may be preferable to do parallel studies of symptoms and pathology in which the treating physician is a person other than the person recording the questionnaire. The recorder may be the patient or another neutral person.

(2) *Other clinical wound-healing studies.* Other studies to test the effects of agents on wound healing must be be designed with the use site in mind, i.e., where there is compression (due to sitting), stretching of surface and subcutaneous tissue on a sporadic basis (due to walking, bowel movement), increased moisture, chafing (due to clothing and opposed body surfaces), and lastly, gross contamination by aerobic and/or anaerobic bacteria and yeast. This is opposed to many body wounds that can be maintained at a relative degree of cleanliness, immobilized, and covered consistently or exposed to air. Although the wound-healing process may be similar in both areas, the natural impediments are not and any experimental design germaine to the anorectal area must consider these impediments. Nonetheless, an agent that causes a significant increase in the healing of wounds at other sites, and also relieves anorectal clinical symptoms over a similar time period can be considered an anorectal wound-healing agent.

Several studies potentially can be carried out using measured skin sites such as a punch biopsy in an easily accessible area on relatively normal skin. Skin graft donor sites, as demonstrated in a submission to the Panel (Ref. 1) may also be used as testing sites. These sites are photographable, and more nearly uniform than other test models. Factors that may be specifically assessed, include swelling, size of site, color, discharge, and epithelialization.

d. *Interpretation of data.* Any effect of the wound-healing rate must be of statistical significance within 7 days. Beyond 7 days, effectiveness is questionable for OTC drug products. If the condition does not improve within 7 days or becomes worse, the consumer is instructed to consult a physician.

(1) *Anorectal studies.* A significantly greater degree of healing in an anorectal area, when p is less than 0.05, allows a Category III agent to be classified Category I if it also produced significant symptomatic improvement in the same or other studies.

(2) *Other clinical wound-healing studies.* Interpretation of other studies must be made with care due to marked differences of sites as noted above. The primary criteria include demonstration of statistically significant healing and correlation of time course of healing with that of clinical improvement, i.e., statistically significant evidence of both types of response with the 7-day limit.

Evidence of effectiveness is required from a minimum of two positive studies based on the results of two different investigators or laboratories. All data submitted must include negative and positive results.

Reference

(1) OTC Volume 120061.

IX. Antiseptics

A. General Discussion

The Panel defines antiseptics as substances that will inhibit the growth and development of microorganisms without necessarily destroying them. The Panel further concludes that this does not imply that only complete inhibition (sterility) is necessary but rather that partial inhibition is satisfactory. Antiseptics usually include a wide variety of agents such an antimicrobials, bacteriostatics, bactericidals, fungistatics, and fungicidals.

The Panel recognizes that many ingredients including soap and water reduce the number of microorganisms (flora) on the skin. The normal skin flora has traditionally been divided into transient and resident flora (Ref. 1). Transient flora are organisms that are not part of the established normal flora and are picked up from the surrounding environment. Transient organisms are removed with relative ease by washing with soap and water (Ref. 1). In contrast, the resident flora is considered to constitute the established population of skin organisms and is more difficult to remove.

Most OTC anorectal drug products contain more than one ingredient and, therefore, may have more than one effect. Some of these products contain substances intended to prevent or counteract infections and are referred to as antiseptics.

The term antimicrobial (antiseptic) refers to activity against microorganisms regardless of their nature, that is, whether they are bacteria, fungi, mycoplasma, rickettsiae, viruses, or animal parasites. The broadest classification of antimicrobial agents is by the nature of their action. "Cidal" agents kill microorganisms, and "static" agents stop microorganisms from multiplying but do not kill them. Thus, the microorganisms may begin to multiply when the static agent is removed from their environment. The nature of microorganisms varies tremendously so there is no one antimicrobial agent that will kill and/or remove all microorganisms. The antimicrobial agents are commonly designated by their most important area of use or intended purpose. Thus, bactericidal agents destroy vegetative bacterial cells but not necessarily bacterial spores. Fungicidal agents are those intended primarily to destroy fungi. Sporicidal agents are those capable of destroying bacterial and fungal spores. Bacteriostatic and fungistatic agents are those capable of inhibiting the growth of bacteria and fungi, respectively. Not only does the nature of the antimicrobial agent determine whether its action is "cidal" or "static," but the concentration of the agent is important. A substance may have a "static" action in high dilution and a "cidal" action in a more concentrated solution (Ref. 2).

Antimicrobial (antiseptic) activity of a drug is usually determined by in vitro testing and is often compared to a standard known as the phenol coefficient, which is the ratio of the killing efficiency of an antimicrobial agent compared to phenol tested under

identical conditions. To document effectiveness, the antiseptic ability of a drug to prevent or counteract infection in the anorectal area must be demonstrated by in vivo testing.

A number of ingredients submitted to the Panel claim antiseptic properties. After a review of the literature and extensive deliberations, the Panel concluded that the maintenance of relative antisepsis in the anorectal area would be ideal for promoting healing by preventing or counteracting infection. However, the likelihood of achieving anorectal antisepsis greater than that obtained by cleansing with soap and water is small due to the frequent anorectal contamination from large numbers of microorganisms present in feces (Ref. 5).

The Panel concludes that the intrarectal application of antiseptic ingredients is scientifically unsound because of the high percent of anaerobic organisms present in the feces. Studies of the importance of anaerobic bacteria in anorectal disease are very few (Refs. 3 and 4). The Panel believes that if in clincial studies claims for antiseptics are made, attention must be paid to these organisms (anaerobes) as well as to the anaerobes that usually have been used in such studies (Refs. 3 and 4).

For anorectal drug products limited to external application, aerobic organisms are more important because anaerobes will not proliferate in the presence of oxygen.

According to the findings of the Advisory Review Panel on OTC Topical Antimicrobial Drug Products as published in the Federal Register of September 13, 1974 (39 FR 33107), there has been widespread use of antimicrobials in soap, surgical scrubs, and preoperative preparations based on the view that the reduction of normal flora to as low a level as possible will have a positive effect on the prophylaxis of disease. However, the Panel further concluded that the interrelationship of the concentration, time of action or contact time, the microbial spectrum, and the possible deleterious effects of drastic changes in the normal flora have been largely ignored in the past or have been superficially investigated. The Advisory Review Panel on OTC Hemorrhoidal Drug Products concurs with the above conclusion and further concludes that the prevention or counteracting of infection in the anorectal area has not been established by the data submitted for ingredients with antiseptic claims.

The Panel recognizes the potential usefulness of antiseptic ingredients on other areas of the body, but due to the unique nature of the anorectal area, effectiveness of these agents cannot be extrapolated because only a partial antisepsis could be achieved at best. The practice of good anal hygiene (cleansing with soap and water) is effective in reducing the number of microorganisms in the anorectal area, and therefore can also aid in the healing process. Thus, although useful in concept, the Panel concludes that proof of any significant clinical benefit of claimed antiseptic ingredients must be demonstrated in clinical trials. (See part IX, paragraph C, below—Data Required for Evaluation.)

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B. Categorization of Data

1. *Category I conditions under which antiseptic ingredients are generally recognized as safe and effective and are not misbranded.*

None.

2. *Category II conditions under which antiseptic ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredients

The Panel has classified the following antiseptic active ingredients as not generally recognized as safe and effective or as misbranded:

Boric acid (external and intrarectal use)
Boroglycerin (external and intrarectal use)
Hydrastis (external and intrarectal use)
Phenol (external and intrarectal use)
Resorcinol (intrarectal use)
Sodium salicylic acid phenolate (external and intrarectal use)

a. *Boric acid (external and intrarectal use).* The Panel concludes that boric acid is not safe and effective as an antiseptic in OTC anorectal preparations.

(1) *Description.* Boric acid occurs as colorless, odorless scales, crystals, or as a white powder. It is stable in air and freely soluble in boiling water, in boiling alcohol, and in glycerin (Ref. 1). Variable amounts of boric acid are used in anorectal preparations (e.g., 50 percent by weight of total active ingredients per suppository, and up to 18 percent in ointments) (Ref. 2).

(2) *Safety.* There are no specific data regarding the safety of boric acid in the treatment of anorectal disorders. However, there is a great deal of information and supportive data regarding its toxicity after local application to skin ulcers or abrasions, and/or ingestion. Boric acid is readily absorbed from the gastrointestinal tract, serous cavities, and abraded skin (Refs. 3, 4, and 5). When ingested orally, boric acid is slowly but completely absorbed and eliminated through the kidney (Ref. 6). The fatal adult oral dose is estimated to be 15 to 20 g but may be much smaller; for infants less than 5 g may be fatal (Refs. 3 through 8). Toxic symptoms and fatal poisoning, especially in infants, following external application on abraded skin of boric acid solutions, ointments, and powders have occurred (Refs. 3, 4, 5, and 7 through 25). A review of the literature on boric acid poisoning by Valdes-Dapena and Arey (Ref. 5) revealed that about one-third of the patients, 53 of 172, had been treated externally. "In 30 of the reported cases, poisoning was due to the application of pure boric acid to the denuded diaper area; 23 of these were fatal and 7 nonfatal" (Ref. 5). According to Ducey and Williams (Ref. 9), a concentration of 5 mg/100 mL blood is a near lethal concentration in an infant, which they calculate can be attained within a few days using 5 percent borated talc dusting powder during diaper changes when dusting is restricted to 100 cm^2 of skin and only 1 percent of the available boric acid is absorbed. However, Johnstone, Basila, and Glaser (Ref. 21) contend that no case of boric acid poisoning has been proven to be the result of any commercially available baby powder containing 5 percent boric acid and conclude from a review of the literature that all of the reported cases of infant mortality attributed to boric acid poisoning have resulted from the injudicious use of boric acid, either from its inadvertent oral administration, intravenous or subcutaneous injection, or from the application of boric acid powder or some homemade preparation containing a high concentration of boric acid to an area of denuded or injured skin.

Anorectal diseases may include inflamed mucosal membranes or abraded skin, which would have a greater ability to absorb boric acid than normal skin (Refs. 3, 5, 7, 8, 16, and 26). The toxic nature of boric acid, as documented by the occurrence of fatal poisonings, particularly in children, has convinced the Panel that it is not safe for use in OTC anorectal preparations.

(3) *Effectiveness.* A review of the literature reveals no clinical data supporting the effectiveness of boric acid in OTC anorectal preparations. While boric acid is claimed to possess weak bacteriostatic and fungistatic activity, it is considered to be of little value as a bactericide (Refs. 6, 7, 8, 10, and 26 through 29). a literature review reveals few controlled studies to support the variety of claims regarding its effectiveness and no definitive data regarding its effectiveness in OTC anorectal preparations. Its therapeutic value is not established, and it has fallen into disrepute because of the occurrence of fatal poisonings, particularly in infants (Refs. 10, 15, 18, 23, 29, 30, and 31).

(4) *Evaluation.* The toxicity of boric acid when applied externally is well documented in the literature. Since anorectal symptoms may be due to inflamed skin and/or mucous membranes that would absorb more boric acid than normal skin, the Panel concludes that boric acid is not safe for anorectal use in OTC anorectal preparations as an antiseptic. Furthermore, there is no evidence in the literature which confirms the effectiveness of boric acid in anorectal products.

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(3) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 4th Ed., The Macmillan Co., New York, p. 1041, 1970.

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b. *Boroglycerin (external and intrarectal use).* The Panel concludes that boroglycerin is not safe and effective as an antiseptic in OTC anorectal preparations.

(1) *Description.* Boroglycerin (boric acid glycerite) is a viscous, yellowish liquid prepared by the splitting out of three molecules of water from the reaction of equimolar amounts of glycerin and boric acid at 140° to 150° C and contains approximately 50 percent boroglycerin. The boroglycerite form is a compound of indefinite composition (Ref. 1). Its formula is assumed to be $C_3H_5BO_3$. It is soluble in water and its solution is acidic in nature (Ref. 2). Boroglycerin is essentially a soluble preparation of boric acid which, when dissolved in water, hydrolyzes into boric acid and glycerin (Ref. 3).

(2) *Safety.* A search of the literature reveals no information regarding the safety of boroglycerin in OTC anorectal preparations. According to Gleason et al. (Ref. 4), boric acid glycerite is moderately toxic with a probably lethal dose of 0.5 to 5 grams/kilogram (g/kg) in a 70 kilogram (kg) man. Aqueous solutions may also be quite irritating (Ref. 5), especially when applied to injured tissue. Because boric acid glycerite hydrolyzes to boric acid when dissolved in water (Ref. 3), the comments made in evaluating the safety of boric acid are applicable. (See part IX. paragraph B.2.a.(2) above—Safety.) The Panel concludes that the 31 percent weight in weight (w/w) content of boric acid (Ref. 6) in this preparation makes it an equally hazardous preparation and not safe for use in OTC anorectal preparations.

(3) *Effectiveness.* Local application, after dilution with water, is reported to have a dehydrating and antiseptic effect, but there is no evidence to support these claims (Ref. 1). It has been used as a suppository base in the preparation of boroglycerin suppositories (Refs. 1 and 2). Because boric acid glycerite hydrolyzes to boric acid when dissolved in water (Ref. 3), the comments made in evaluating the effectiveness of boric acid are applicable. (See part IX. paragraph B.2.a.(3) above—Effectiveness.) Therefore, the Panel concludes that the effectiveness of boroglycerin in OTC anorectal

preparations is not supported by definitive clinical data.

(4) *Evaluation.* The Panel concludes that due to the content of boric acid in boroglycerin, it is not safe and effective for use in OTC anorectal preparations as an antiseptic. (See part IX. paragraph B.2.a. above—Boric acid (external and intrarectal use).)

References

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c. *Hydrastis (external and intrarectal use).* The Panel concludes that hydrastis is not safe or effective for external or intrarectal use as an antiseptic in OTC anorectal preparations.

(1) *Description.* (See part VI. paragraph B.2.b.(1) above—Description.)

(2) *Safety.* (See part VI. paragraph B.2.b.(2) above—Safety.)

(3) *Effectiveness.* The Panel has found no evidence that hydrastis is effective as an antiseptic. (See part VI. paragraph B.2.b.(3) above—Effectiveness.)

(4) *Evaluation.* The Panel concludes that hydrastis is not effective for use in OTC anorectal preparations because no clinical data supporting such use as an antiseptic are available.

d. *Phenol (external and intrarectal use).* The Panel concludes that phenol is not safe as an antiseptic in concentrations of 1.5 percent or greater and is ineffective at this concentration for use in OTC anorectal preparations.

(1) *Description.* Phenol is a colorless, crystalline compound having a characteristic odor. It is soluble to the extent of approximately 6 g/100 g water. It is miscible with alcohol or glycerin. A mixture of liquified phenol and an equal volume of glycerin is miscible with water (Refs. 1, 2, and 3).

(2) *Safety.* The Panel concludes that phenol in concentrations greater than 1.5 percent in aqueous or alcoholic vehicles is not safe. The data supporting this decision may be found in various standard reference tests that document the toxicity of phenol when applied topically to skin or mucous membranes (Refs. 1 through 5).

Deichmann and Keplinger (Ref. 3) demonstrated the ability of the descending rabbit colon to absorb phenol faster than the stomach or ileum. Although 1 g may be fatal to humans and exceptional patients have survived 65 g, 50 percent of all cases reported through 1929 terminated fatally (Ref. 3). One to 5 percent phenol applied as a dressing or compress has caused gangrene (Ref. 3). Five percent in oil when injected to relieve hemorrhoids has caused serious problems including gangrene and liver enlargement (Ref. 6). Phenol also penetrates the sensory nerve endings and exerts a local anesthetic action (Ref. 7). High percentage oily solutions (e.g., 50 percent) are used to destroy keratin down to the corium for cosmetic repair (Ref. 5). Phenol is less soluble in water than in alcohol and penetrates deeply into the skin producing severe burns, and is absorbed in higher concentrations producing systemic effects (Ref. 4).

Systemically, phenol can cause central nervous system depression. It decreases blood pressure partly as a result of central vasomotor depression, but mainly due to a direct toxic action on the myocardium and the smaller coronary blood vessels. Because it is lipid soluble, phenol can be absorbed into the circulation even from intact skin (Ref. 1).

(3) *Effectiveness.* Phenol acts both systemically and locally. Phenol disassociates from combination with protein and has great penetrability into tissues. When applied directly to skin, a white pellicle (layer) of preicipitated protein is formed. If phenol remains in contact with skin for a prolonged period of time, phenol penetrates deeply and may cause extensive necrosis (Refs. 1, 3, and 4).

(4) *Evaluation.* Phenol is rarely used as an antiseptic. It was widely used and accepted as an antiseptic when little else was available. Now it is obvious that the level of phenol required in an antiseptic formulation to be effective (i.e., 2 percent or greater) is higher than the level that can be safely used on skin or mucous membranes. Phenol is toxic in concentrations greater than 1.5 percent (Ref. 5).

Refereneces

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e. *Resorcinol (intrarectal use).* The Panel concludes that resorcinol is not safe or effective for intrarectal use as an antiseptic in OTC anorectal preparations.

(1) *Description.* (See part X. paragraph B.1.b. (1) below—Description.)

(2) *Safety.* (See part X. paragraph B.1.b. (2) below—Safety.) Absorption of resorcinol may occur through the skin, through open wounds, or from the gastrointestinal tract (Refs. 1, 2, and 3). Resorcinol resembles phenol in its physiologic properties so that the effects are very similar (Ref. 1). Phenol absorption from the bowel takes place rapidly and in a few instances has led to severe and fatal poisoning after such superficial exposure that hypersensitivity or idiosyncracy is suggested (Ref. 2).

Resorcinol has been employed in the past in various preparations taken by mouth but is no longer available because of potential for toxicity. At present it is used in some intrarectal applications. However, rapid absorption occurs from mucous membranes (Refs. 2 and 4). A 3 percent concentration in 1 ounce (oz) (28.5 g) of ointment would provide 840 mg of resorcinol; this is a toxic dose if it were inserted in the rectum and absorbed rapidly (Ref. 2). The Panel agrees with a standard pharmaceutical reference that states that resorcinol has no legitimate internal use (Ref. 5).

(3) *Effectiveness.* Resorcinol resembles phenol in its physiologic properties, though it is less active (Refs. 3, 4, and 6). Klarmann, Gatyas, and Shternov (Ref. 7) found that the phenol coefficient against *Typhoid bacillus* or *Staphylococcus aureus* was 0.4. Therefore, the effective concentration of resorcinol would be two and one-half times that of phenol. Insofar as aqueous

solutions of phenol are concerned, they are bacteriostatic in vitro in a 0.2 to 1.0 percent concentration, and bactericidal but unsafe at higher concentrations (Ref. 1). Though its actions will vary depending on organisms present and temperature, it would seem reasonable to concude that 0.5 to 2.5 percent resorcinol on intact skin would be bacteriostatic, although its potency as a bactericide would be marginal. However, there is no evidence to document intrarectal effectiveness on mucous membranes.

(4) *Evaluation.* Because of the constant contamination in the rectum, the Panel concludes that intrarectal use is of no value and use of resorcinol in that location as an antiseptic is not warranted.

References

(1) "Martindale. The Extra Pharmacopoeia," 26th Ed., Edited by Blacow, N. W., The Pharmaceutical Press, London, England, p. 201, 1972.

(2) Gleason, M. N. et al., "Clinical Toxicology of Commercial Products. Acute Poisoning," 3d Ed., The Williams and Wilkins Co., Baltimore, MD, pp. 124 and 189–192, 1969.

(3) DiPalma, J. R., "Drill's Pharamcology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1640, 1971.

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f. *Sodium salicylic acid phenolate (external and intrarectal use).* The Panel concludes that sodium salicylic acid phenolate is not safe as an antispetic and that there is insufficient evidence to prove effectiveness for use in OTC anorectal preparations.

(1) *Description.* Sodium salicylic acid phenolate is not a known or recognized chemical entity found in the published literature. In the submission to the Panel, from the listed ingredients used to prepare sodium salicylic acid phenolate, it is difficult to determine what chemical reactions actually may occur (Ref. 1). The Panel will evaluate sodium salicylic acid phenolate based on its phenol and salicylic acid components.

(2) *Safety.* No published references were found regarding the safety of this compound; however, it is expected that the effects would be similar to the combination of phenol and salicylic acid. According to information submitted by a manufacturer who utilizes this compound, an analysis reveals that the compound contains nearly all of its phenol as free phenol (Ref. 2). The amount of phenol is reported to be 3.35 percent (Ref. 2). As discussed elsewhere in this document, phenol is not considered safe in concentrations greater than 1.5 percent (Ref. 3). (See part IX. paragraph B.2.d.(2) above—Safety.) Phenol is rarely used as an atiseptic because it has relatively feeble activity, and it possesses undesirable tissue toxicity when used in an effective antiseptic concentration (Refs. 4, 5, and 6).

Salicylic acid is irritating to skin and mucosa, destroying epithelial cells (Ref. 3). It is a keratolytic agent, causing tissue cells to swell, soften, and desquamate (Ref. 3).

(3) *Effectiveness.* No published studies affirming the effectiveness of sodium salicylic acid phenolate have been found.

Salicylic acid is not a recognized antiseptic agent.

Phenol is no longer commonly used as an antiseptic. It is obvious that the level of phenol required in a formulation to be effective as an antiseptic (i.e., 2 percent or greater) is sufficiently high so that it cannot be used safely on the skin or mucous membranes; concentrations greater than 1.5 percent are not generally recognized as safe.

(4) *Evaluation.* The Panel concludes that sodium salicylic acid phenolate is not safe or effective for use as an antiseptic or anorectal ingredient.

References

(1) OTC Volume 120017.

(2) OTC Volume 120043.

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(5) "Remington's Practice of Pharmacy," 13th Ed., Edited by Martin, E. W. and E. F. Cook, Mack Publishing Co., Easton, PA, pp. 1440–1441, 1965.

(6) Wright, A. D., "Complications of Rectal Infection," *Proceedings of the Royal Society of Medicine*, 43:263–266, 1950.

Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of anorectal drug products are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel concludes the following claims to be misleading and unsupported by scientic data.

a. The term "antiseptic" and/or "antisepsis" is not acceptable. The Panel concludes that this term has many varied meanings ranging from partial (static) to total (cidal) effects and has no usefulness in anorectal OTC products because of the large number of organisms that normally exist in the anorectal area.

b. The term "kills" implies a total antisepsis that is useless in the anorectal area even if achieved because of the large number of organisms that normally exist in this area.

c. "Reduces inflammation, kills bacteria, deadens pain and rapidly removes annoying irritation." This claim cannot be justified when associated only with the term antiseptic.

d. "Not only an antiseptic action . . ." This claim is misleading because it implies too wide an effect that cannot be proved and is not useful in anorectal products.

e. "Controls infection" is unacceptable for conditions amenable to OTC treatment; infections require supervision by a physician.

f. The following are claims that are unproven and, due to contamination of the anorectal area following bowel movements, are only an unsubstantiated relative antibacterial activity at best:

(i) "Forms a protective antibacterial film over raw inflamed tissue."

(ii) "Possesses a highly bactericidal and fungicidal effect on the germs, fungi, yeasts, molds, and pathogens present in the infected area."

(iii) "Prevents overt skin infection."

(iv) "Degerming in the anorectal area."

(v) "Bacteriostatic in the anorectal area."

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredient

The Panel concludes that the available data are insufficient to permit final classification of the following antiseptic active ingredient named below. The Panel believes it is reasonable to provide 2 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 2 years,

however, the ingredient listed in this category should no longer be marketed in OTC products.

Resorcinol (external use). The Panel concludes that resorcinol is safe for external use as an antiseptic but that there is insufficient evidence to prove effectiveness for use in OTC anorectal preparations.

(1) *Description.* (See part X. paragraph B.1.b. (1) below—Description.)

(2) *Safety.* (See part X. paragraph B.1.b. (2) below—Safety.)

(3) *Effectiveness.* Resorcinol resembles phenol in its physiologic properties, although it is less active (Refs. 1, 2, and 3). Klarmann, Gatyas, and Shternov (Ref. 4), found that the phenol coefficient against *Typhoid bacillus* or *Staphylococcus aureus* was 0.4. Therefore, the effective concentation of resorcinol would be two and one-half times that of phenol. Insofar as aqueous solutions of phenol are concerned, they are bacteriostatic in vitro in a 0.2 to 1.0 percent concentation, and bactericidal at higher concentrations (Ref. 5).The Panel has received letters from recognized dermatologic experts who state that resorcinol is a mild antiseptic in concentrations of 1 to 5 percent (Refs. 6, 7, and 8). Though its actions will vary, depending on organisms present and temperature, it would seem reasonable to conclude that resorcinol in a 0.5 to 2.5 percent concentration would be bacteriostatic, but its potency as a bactericide would be marginal (Refs. 2 and 4). However, in the anorectal area frequent contamination makes resorcinol less effective as an antiseptic. No data were found to indicate the effectiveness of resorcinol less effective as an antiseptic. No data were found to indicate the effectiveness of resorcinol in this area as an antiseptic. If further bacteriologic studies indicate a reduction in the number of bacteria in the perianal area after application of resorcinol, claims for temporary reduction in the number of bacteria, bacteriostatic, degerming, or reduction in the risk of infection could be made. (see part IX. paragraph C. below—Data Required for Evaluation.)

(4) *Proposed Dosage.* Adult external dosage is 0.5 to 2.5 percent per dosage unit not to exceed 50 mg per dosage unit and not to exceed six applications per 24 hours.

(5) *Proposed labeling.* The Panel recommends the Category III labeling for antiseptic active ingredients, pending testing for effectiveness. (See part IX. paragraph B.3. below—Category III Labeling.)

(6) *Evaluation.* The value of any antiseptic in the perianal area is open to question. Heavy contamination and recontamination are the rule so that any claim as an antiseptic needs careful substantiation. The Panel was unable to find any pertinent evidence concerning the bactericidal effect of resorcinol in perianal disease. Because there is a possibility that such evidence could be found, resorcinol is being placed in Category III for external use. Tests to elevate resorcinol to Category I for external use as an antiseptic must include bacteriologic studies to prove bacteriostatic or bactericidal effects for a suitable period of time for gram-negative bacteria, and prove that replacement of these bacteria by other pathogenic organisms or fungi does not occur. These tests are described in detail later in this document. (See part IX. paragraph C. below—Data Required for Evaluation.)

References

(1) "The United States Dispensatory," 27th Ed., Edited by Osol, A. and R. Pratt, J. B. Lippincott Co., Philadelphia, PA, pp. 1017–1018, 1973.

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(3) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1640, 1971.

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(6) Letter to DeCillis, T. D. from A. A. Fisher dated March 9, 1977 is included in OTC Volume 120051.

(7) Letter to Decillis, T. D. from E. F. Traub dated March 9, 1977 is included in OTC Volume 120051.

(8) Letter to DeCillis, T. D. from R. B. Rees dated March 14, 1977 is included in OTC Volume 120051.

Category III Labeling

The Panel concludes that the available data are insufficient to permit final classification of the claims listed below. Additional data are required to support the following antiseptic claims:

a. "Temporarily reduces the number of organisms in the perianal area."

b. "Reduces the risk of infection."

C. Data Required for Evaluation

The Panel has agreed that the protocols recommended in this document for the studies required to substantiate Category I are in keeping with the present state of the art and do not preclude the use of any advances or improved methodoldgy in the future.

Relative antisepsis. Demonstration of this effect must be carried out in human subjects because of the unique environment of the anorectal area. Proof of relief after repeated applications will be required in addition to noting changes in bacterial counts after one application; the primary purpose is for testing of claims for antisepsis. Therefore, bacteriological colony counts per cm on a sterile 1 cm square pledgett applied to the skin at the anal verge immediately, 30 minutes, 2 hours, and 6 hours after use of the ingredient on the area compared with use of water only or no treatment and exclusion of recent defecation will provide a reasonable measure of this property. If significant differences in bacterial count were found in a statistically significant number of trials, this claim is permitted. However, the claim would have to reflect the actual duration of not less than 30 mimutes of the antiseptic effect found in the studies to the extent that it was statistically superior to soap and water. Consideration of aerobic and anaerobic organisms must also be evaluated.

b. An alternate technique was suggested by Engley (Ref. 1) utilizing a neutralizing medium. A special medium is important to determine the effectiveness of the active ingredient as opposed to the effect of preservatives in the final product.

Five organisms, *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia col, Proteus vulgaris,* and *Pseudomonas aeruginosa,* which are most frequently associated with skin or the perianal area, are streaked with a swab on a blood-agar plate. A 12.5 mm disc, previously coated with a layer of a final formulation product, is placed face down in the center of the streak. The plate is then incubated for 18 hours at 98.6° F (37° C). The zone of inhibition around the disc will give an approximate degree of antimicrobial activity.

Formulations showing inhibition would then be tested for effectivenes in the perianal in the following manner: A cotton swab is used to obtain a sample of the microbial flora of the skin in the test area. The product is applied to the skin for a predetermined length of time (e.g., 20 minutes) and then removed. A second sample is taken immediately after 1, 2, and 4 hours have elapsed. The swab is used to streak a 12 mm zone on a blood-agar plate and then placed on the agar after cutting the stick off the swab. Incubation is done at 98.6° F (37° C) for 18 hours.

Positive results will have to be verified against a special neutralizing media to eliminate the effect of preservatives from the effect of active ingredients. The duration of antisepsis, if achieved, can be evaluated by this technique.

It has not yet been established how long antimicrobial activity must be exhibited and the minimum zone of inhibition required to permit antisepsis claims in the anorectal area. In view of the lack of established procedures for investigating this area, the Panel recommends that FDA work with interested parties to develop the details necessary to illustrate the principles in both techniques discussed here, i.e., (1) the presence of organisms and types after using an anorectal antiseptic and (2) the zone of inhibition on standard organisms.

Reference

(1) Engley, F. B., Presentation to the Panel, July 9, 1976, is included in OTC Volume 120051.

X. Keratolytics

A. General Discussion

The Panel has defined keratolytics as agents that cause desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis. The epidermis consists of stratified squamous cells that contain keratin (Ref. 1). Certain substances, especially the phenols and sulfhydryl compounds, loosen keratin, resulting in debridement and desquamation of epithelial tissue (Ref. 1). Adriani (Ref. 2) was able to demonstrate that resorcinol, which belongs to the class of dihydric phenols, in concentrations of 1 to 3 percent may have some ability to reduce itching as does phenol, although resorcinol is slightly less toxic. Keratolytics are claimed to be useful in many conditions where the keratin layer has proliferated to a great extent, such as warts, corns, psoriasis, eczema, and acne (Refs. 1, 3, and 4) and are being reviewed by other OTC review panels. Because they help remove keratin-containing cells, it is theorized that keratolytics help expose underlying tissue to therapeutic agents; the combination of two or more active ingredients is discussed elsewhere in this document. (See part II. paragraph K. above—Principles Applicable to Combination Products.)

In a presentation to the Panel, Maibach stated that many chemicals are not considered to be keratolytics in the concentrations usually employed and at present there are apparently no good quantitative methods to study the mechanism of action of keratolytics in treating itching (Ref. 5). Maibach could not explain the therapeutic value of using keratolytics on perianal skin, which is usually moist and sometimes macerated, but Maibach thought that keratolytics were of some value in ichthyosis in which the skin is characterized by dryness, roughness, and scaliness due to excessive thickness (hypertrophy) of the horny layer (Ref. 5). The Panel concludes that keratolytics at the concentrations specified in the following ingredient discussions, for external use, are useful in reducing itching, but a claim for keratolysis requires additional study.

Keratolytics have been used intrarectally in OTC anorectal products. The Panel believes it is highly irrational therapy, however, because there is no keratin layer on mucous membranes. Keratolytics are used externally in certain cases of anal hyperkeratinization for example in psoriasis, acne, seborrheic dermatitis, and eczema. However, many anorectal diseases are associated with excoriation or mild inflammation in which dekeratinization has occurred. The Panel also recognizes that there may be conditions in which too high a concentration of keratolytics might produce irritation that would be detrimental to healing. For this reason, safe and effective concentrations of keratolytics to relieve itching or to achieve keratolysis must be carefully established.

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B. Categorization of Data

1. *Category I conditions under which keratolytic ingredients are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I Active Ingredients

The Panel has classified the following keratolytic active ingredients as generally recognized as safe and effective and not misbranded:

Alcloxa (external use)

Resorcinol (external use)

a. *Alcloxa (external use).* The Panel concludes that 0.2 to 2.0 percent alcloxa per dosage unit is safe and effective for external use as a keratolytic for the relief of itching in OTC anorectal preparations and not to exceed six applications per 24 hours.

(1) *Description.* Alcloxa (aluminum chlorhydroxy allantoinate) is a clean, white powder that is soluble in water and to a lesser extent in alcohol. It is insoluble in ether and chloroform (Ref. 1). Allantoin (5-ureidohydantoin) is a uric acid derivative and is chemically known as the diureide of glyoxyllic acid. In the racemic form, allantoin appears as monoclonic prisms or plates; it is in the form of colorless crystals (Refs. 2, 3, and 4).

In 1568, the virtues of comfrey root, the natural predecessor of allantoin, as a keratolytic and protectant were described (Ref. 1). During the Civil War it was observed that wounds that were infested with living maggots (maggots excrete allantoin) healed rapidly (Ref. 1).

(2) *Safety.* No reports have been found indicating any significant toxicity of allantoins as keratolytics in topical preparations in a concentration range of 0.2 to 2.0 percent. Patch testing and repeated insult testing on humans showed that allantoin is nontoxic, nonirritating, and nonallergenic and that it was not a primary skin sensitizer (Ref. 4). Testing on rabbits showed that allantoin is nonirritating to the eye (Ref. 4).

Allantoin has been demonstrated as having a keratin and protein dispersal effect (Ref. 4). The dispersal effect is in part due to action on the soluble cement substance (keratin matrix) which is responsible for the adherence of the cornified cells in the stratum corneum to each other (Ref. 5). There have been no reports of the growth of abnormal tissue or tumors with the use of allantoin (Ref. 4).

In animal experiments (Ref. 4), aluminum chlorhydroxy allantoinate was applied to a 4 square inch (in^2) shaved area on the backs of adult male guinea pigs, and the chemical agent proved to be without any primary irritating or sensitizing properties.

(3) *Effectiveness.* The Panel concludes that allantoin can reduce itching, although the mechanism is unclear. A therapeutic quality of the allantoins is

said to be a healing effect, which is attributed to cell proliferant action and its effectiveness in removing necrotic tissue (Ref. 2). It is reported to be safe, soothing, and nonirritating even after relatively constant use for extended periods of time (Ref. 4). Aluminum chlorhydroxy allantoinate and other aluminum derivatives of allantoin, in addition to the therapeutic properties of allantoin, are said to exert astringent, buffering, and deodorant effects (Ref. 1). It is reported safe and effective in the forms of powder, solution, suspension, cream, lotion, or ointment (Ref. 3).

The Keratolytic activity of aluminum chlorhydroxy allantoinate is related to the fact that the allantoin is a hydrogen bond breaker. It probably acts by a desolvating action on the mucopolysaccharide, whose presence has been indicated in the intercellular cement of the stratum corneum (Ref. 4).

Allantoin also has a protein denaturing effect on the soluble proteins in the cement matrix by splitting their disulfide linkages, as evidenced by exposure of sulfhydryl groups whose presence can be determined by appropriate chemical means (Refs. 4 and 6).

When allantoin is applied to ulcers, wounds, cuts, and lacerations, it is claimed to have the ability to remove the undesirable necrotic tissue, clean up the area, and then follow through by inducing new tissue growth.

Another reported activity is that it appears to produce a medium distinctly unfavorable to bacterial growth. Allantoin is also said to possess leukocytic stimulating properties, particularly by stimulating healthy neutrophils (Ref. 4). The mechanism by which allantoin relieves itching is not clear, but the property of aiding in the removal of necrotic tissue and/or the possible stimulation of healing could lead to this effect. Data submitted contain studies on a range of concentration used from 0.2 to 2.0 percent (Refs. 4 and 7).

(4) *Dosage.* Adult external dosage is 0.2 to 2.0 percent per dosage unit and not to exceed six applications per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for keratolytic active ingredients. (See part X. paragraph B.1. below—Category I Labeling.)

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b. *Resorcinol (external use).* The Panel concludes that 1 to 3 percent resorcinol per dosage unit is safe and effective for external use as a keratolytic for the relief of itching in OTC anorectal preparations and not to exceed six applications per 24 hours.

(1) *Description.* Resorcinol is *m*-dihydroxybenzene. It occurs as white or pearly white, needle-shaped crystals or powder. One g dissolves in about 1 mL of water or alcohol. It is freely soluble in glycerin and ether and slightly in chloroform (Regs. 1 through 3).

(2) *Safety.* Therapeutic results and toxicity are closely related to the concentration of the agent employed and the site of application. The amount used must be limited because the toxicity of resorcinol is high. Absorption has led to methemoglobinemia, exfoliative dermatitis and death in infants, and to myxedema after repeated application in adults. Resorcinol can be absorbed rapidly from mucous membranes and is more dangerous than application to the intact skin. Severe allergic reactions may occur (Refs. 1, 4, 5, and 6).

In rats the subcutaneous minimal lethal dose is 450 mg/kg. The probable lethal dose of resorcinol in humans is between 50 to 500 mg/kg in a 7-kg man (Ref. 4). Dreisbach (Ref. 7) accepts a lower minimal figure of 2 g in a 70-kg man. The total maximum daily dose, even assuming complete absorption, to which an adult is exposed when resorcinol is used according to the recommended dosage set by the Panel is 360 mg in a 70-kg man (5.14 mg/kg). Therefore, the Panel concludes that resorcinol is safe at the recommended dosage because the total maximum recommended dose of 360 mg is considerably less than the 2-g toxic dose set by Dreisbach (Ref. 7).

Absorption of resorcinol may occur through the skin, through open wounds, or from the gastrointestinal tract. Resorcinol resembles phenol in its physiologic properties so that the effects are very similar (Ref. 1). Phenol absorption from the bowel takes place so rapidly, and in a few instances has led to severe and fatal poisoning after such superficial exposure, that hypersensitivity or idiosyncracy is suggested (Ref. 4). Similarly, after two applications of resorcinol to nearly intact skin, Kyrle (Ref. 5) noted poisoning in a 2-day-old infant.

The symptoms of mild resorcinol poisoning are ringing in the ears, some acceleration of breathing or pulse, and profuse sweating. With large doses, methemoglobinemia, circulatory collapse, unconsciousness, and violent convulsions may occur. Enough resorcinol may be absorbed from the essentially intact skin or from ulcerations to produce toxic effects (Refs. 1, 4, 5, and 6).

In vitro exposure of red blood cells to resorcinol produced a gradual swelling and an increase of the cell volume by 25 percent. This was followed by hemolysis (Ref. 8).

Fatal resorcinol poisoning has been reported in infants, though the Panel has found no report of deaths in adults. Cunningham (Ref. 9) reported a case of an infant who, after application of a compound containing 12.5 percent resorcinol (a total of 1.0 to 1.25g), developed methemoglobinemia and exfoliative dermatitis. Recovery was still incomplete 6 months later. Cunningham (Ref. 9) collected from the literature eight somewhat similar infant cases. Most of the infants had perianal eczema or diaper rash; seven of them died shortly after application. The concentration of resorcinol, known in three instances, was 2 percent, 3 percent, and 5 percent, but the quantity used resulted in toxicities. Castellani's solution which contains 10 percent resorcinol, led to methemoglobinemia with conversion of 41 percent of the hemoglobin when painted twice on a 6-month-old infant (Ref. 10).

Several adults have developed myxedema due to the antithyroid action of the drug following absorption when applied repeatedly to varicose ulcers (Refs. 11, 12, and 13). In rats subcutaneous injections of resorcinol diacetate markedly reduced radioactive iodine uptake in the thyroid, and injections twice daily at a dose of 0.4 millimoles per 100 grams produced thyroid hyperplasia in 12 days (Refs. 14 and 15).

Resorcinol, like phenol (Ref. 4), can produce a severe allergic reaction either immediately or after subsequent application (Ref. 7). Considering the large number of applications of resorcinol in various preparations, the overall sensitizing potential, however, is low (Refs. 1 through 4).

An unpublished study on 51 patients suggests that clincially significant irritation occurs at concentrations greater than 5 percent resorcinol when applied as an occlusive patch for 48 hours (Ref. 16). This is further evidence that resorcinol is safe in concentrations of 1 to 3 percent recommended by the Panel.

In summary, the Panel concludes that resorcinol used externally in adults in a 1 to 3 percent concentration in anorectal OTC drug products is safe when accompanied by a warning, "Do not use in open wounds near the anus," and notes that numerous clinical trials (Refs. 17, 18, and 19) of preparations containing such concentrations of resorcinol testify to its safety.

(3) *Effectiveness.* A major action of resorcinol is as a keratolytic agent (Refs. 1, 2, and 3). Resorcinol is considered to have an antipruritic action and although the exact mechanism of its ability to relieve itch is not known, the Panel finds that resorcinol is effective for this purpose (Refs. 17 through 22). With pastes that contain as much as 45 percent resorcinol, the entire thickness of skin may be destroyed (Ref. 23). Application of resorcinol, though effective, must be limited to very short periods (e.g., 24 hours or less) because of absorption and toxicity (Refs. 1, 2, and 3).

There is no complete agreement concerning the lowest concentration in which resorcinol is effective as a keratolytic. Several authorities consider the lowest level to be 1 percent. Grollman and Grollman (Ref. 24) accept a 1 to 5 percent concentration for a keratolytic effect; others accept a 2 percent level (Refs. 1 through 3). The Panel received letters from recognized dermatology experts who state that resorcinol is a mild keratolytic in concentrations of 1 to 3 percent (Refs. 17, 18, 20, 21, 22, and 25). Ormsby and Montgomery (Ref. 19) state that it is keratoplastic in solutions of 2 to 4 percent concentration and is keratolytic in a strength of 10 to 50 percent.

Keratolytics in the anorectal area are of value in the treatment of psoriasis or for the removal of the outer layer of the thickened epidermis (Refs. 1 and 26). The Panel is aware that OTC products for the treatment of psoriasis are being reviewed by another OTC advisory review panel and that claims for psoriasis will be more appropriately reviewed by that Panel.

Many cases of anorectal disease are characterized by skin abrasions or infection in which excessive keratolysis theoretically could exert adverse effects that should be under physician supervision. For this reason, the Panel has accepted low concentrations of resorcinol (1 to 3 percent) as of value in anorectal products for external use.

(4) *Dosage.* Adult external dosage is 1 to 3 percent per dosage unit and not to exceed six applications per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for keratolytic active ingredients. (See part X. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following warnings: (i) *"Caution:* Certain persons can develop allergic reactions to ingredients in this product. If redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician."

(ii) "Do not use in open wounds near the anus." The warning is considered necessary to preclude absorption of resorcinol through broken skin.

(6) *Minority report on resorcinol.* The minority concludes that resorcinol has no proven effectiveness as a kerotolytic at 1 to 3 percent concentrations, which are possibly safe for topical use, although the safety for OTC use is also unproven.

(i) *Safety.* Resorcinol, like phenol, is a toxic substance whose adverse effects can result from both exposure to an excessive dose on one occasion or chronic exposure to lower doses (Refs. 1, 4, 5, 6, 11, 12, and 13). Although these hazards can be weighed against therapeutic benefits when physician-supervised dermatologic therapy is undertaken, the minority of the Panel concludes that the safety of 1 to 3 percent resorcinol for external use in the OTC market remains to be established.

(ii) *Effectiveness.* Resorcinol is an effective keratolytic by virtue of its ability to alter keratin and increase the pliability, or plasticity, of the keratin layer of skin (Ref. 5). This effect also secondarily interrupts the keratin epithelial barrier of the skin to allow increased absorption of itself and any other substances present. The ability to soften keratin is a useful property in the treatment of disorders characterized by hyperkeratinization, such as psoriasis or simple callouses.

The anorectal area is characteristically moist due to anatomical factors and occlusion by clothing. This fact helps contribute to the pliability of the skin surface in this area. The anorectal area is only rarely plagued by disorders of hyperkeratinization such as psoriasis or venereal disease, which are usually treated by a physician. The former is more likely treated with steroids rather than keratolytics. If the latter (venereal disease) is treated with a keratolytic, it is applied in concentration only to the lesion for a specific time period and removed to avoid toxicity. The more common lesions of the anorectum such as anal fissures, enlarged hemorrhoidal veins, and perianal skin irritation of a moist type are not pathologically characterized by hyperkeratinization. Therefore, the minority are unable to conclude a keratolytic has any rationale for OTC anorectal use.

A further problem arises when the amount used for purported keratolytic effects is considered. There is controversy in the secondary resource literature regarding the lowest effective keratolytic concentration, which ranges from an estimate of 1 to 10 percent (Refs. 1, 2, 3, 5, and 25). Much of the confusion arises due to the lack of any careful studies to establish this fact. The majority opinion of the Panel is that resorcinol is safe at concentrations less than 3 percent and effective as a keratolytic in concentrations of 1 to 3 percent. There are no studies found which establish this property at this concentration on any body site or in the anorectal area.

Therefore, it is the opinion of three Panel members that proof of effectiveness of resorcinol as a keratolytic for use in the anorectal area needs to be established with regard to both therapeutic usefulness and rationale for the OTC market and, if established, the effectiveness of the proposed safe dose in the anorectal area.

(iii) *Studies needed for proof of safety and effectiveness—(a) Safety.* The primary safety concerns relate to absorption of resorcinol systemically. If any absorption from abraded skin areas can demonstrate quantities of resorcinol in blood level or urinary excretion, then that quantity of resorcinal should be studied to determine whether toxic effects will occur. Methods to determine the effects could include red cell function, and liver and renal function tests. Since resorcinal has been reported to induce goiten and tinnitus, thyroid function test and auditory function test could also be used. If absorption is not demonstrated, it must be established, by use of animal models if needed, that the lower limit of sensitivity of assay method would measure blood or urine levels expected with administration of known toxic levels. For example, in rats, the minimal lethal dose is 450 mg/kg. By administration of lower amounts and measurements of kinetics, estimates of volume of distribution and correlation of blood level with total dose can be made, and a toxic blood concentration can be estimated and correlated with dose. If the method is adequately sensitive and

no absorption is demonstrated, this would be acceptable evidence of relative safety.

(*b*) *Effectiveness.* (*1*) Statistically significant clinical improvement in symptoms of anorectal disease with resorcinol in final formulation compared to final formulation alone, in double-blind clinical trials as well as demonstration that this improvement is due to keratolysis, would be necessary to substantiate a claim for improvement in symtoms due to keratolysis, although only the former is needed to claim symptomatic improvement.

(*2*) The effectiveness of 1 to 3 percent resorcinol in formulation giving symptomatic improvement and achieving keratolysis must be demonstrated if a claim is made for effectiveness by virtue of keratolysis.

(*3*) The property of keratolysis may be demonstrated histologically and possibly by a test of tensile strength or compressibility and could be done on skin from other body sites.

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(18) Letter to DeCillis, T. D. from A. A. Fisher, dated February 20, 1976 is included in OTC Volume 120051.

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(20) Letter to DeCillis, T. D. from R. B. Rees, dated March 14, 1977 is included in OTC Volume 120051.

(21) Letter to DeCillis, T. D. from E. F. Traub, dated March 9, 1977 is included in OTC Volume 120051.

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Category I Labeling

The Panel recommends the following Category I Labeling for keratolytic active ingredients to be generally recognized as safe and effective and not misbranded.

Indication. "For the temporary relief of itching."

2. *Category II conditions under which keratolytic ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredients

The Panel has classified the following keratolytic active ingredients as not generally recognized as safe and effective or as misbranded:

Precipitated sulfur (intrarectal use)
Sublimed sulfur (intrarectal use)
Resorcinol (intrarectal use)

a. *Precipitated sulfur and sublimed sulfur (intrarectal use).* The Panel concludes that Precipitated sulfur and sublimed sulfur are not effective for intrarectal use as keratolytics in OTC anorectal preparations.

(1) *Description.* The element sulfur exists in a variety of physical forms and is used in fine powders (sublimed or precipitated sulfur), in colloidal form with aqueous solutions, and in ointments (Ref. 1). It is insoluble in water an most organic solvents and may contain small amounts of hydrocarbons and occasionally selenium or arsenic (Ref. 2). It has been used an an antimicrobial agent and more recently as a keratolytic agent for cutaneous disorders (Ref. 1).

(2) *Safety.* No information applicable to safety in anorectal use has been found, although effets when used elsewhere are or relevance to both intrarectal and external use. When given orally, sulfur is reported to have a cathartic effect, probable secondary to formaton of sulfides or sulfates by intestinal bacteria (Refs. 3 and 4), but no maximal toxic dose has been established. It is possible that intrarectal sulfur breaks down in the presence of bacterial flora, which could cause the rare and relatively benign sulfhemoglobinemia (Refs. 1 and 5), although this is unusual in humans (Ref. 6).

When used on human skin, it has been found that elemental sulfur can cause perpetuation and production of acne and follicular obstruction at concentrations greater than 0.5 percent (Ref. 7). Accordingly, concentrations must be kept below this level. A keratolytic agent is judged by the Panel to be deleterious on rectal mucosa.

(3) *Effectiveness.* Clinical studies related to the use of sulphur on rectal mucosa could not be found in the literature. This, plus the lack of any apparent function as judged by the Panel, formed the basis for the Panel's decision that sulfur has no apparent usefulness when used intrarectally.

(4) *Evaluation.* It is irrational to use keratolytics intrarectally. The Panel finds no data to support the safety or effectiveness of the intrarectal use of sulfur.

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b. *Resorcinol (intrarectal use).* The Panel concludes that resorcinol is not safe or effective for intrarectal use as a keratolytic in OTC anorectal preparations.

(1) *Description.* (See part IX. paragraph B.2.e.(1) above—Description.)

(2) *Safety.* (See part IX. paragraph B.2.e.(2) above—Safety.) Resorcinol has been employed in the past in various preparations taken by mouth. At present it is used in some intrarectal applications. Rapid absorption occurs from mucous membranes (Ref. 1). A 3 percent concentration in 1 oz (28.5 g) of ointment would provide 840 mg of resorcinol, a toxic dose if it were absorbed rapidly from the rectal mucosa. The Panel agrees with a standard pharmaceutical text that states that resorcinol has no legitimate internal use (Ref. 2).

Resorcinol can produce a severe allergic reaction either immediately or after subsequent application. Considering the large number of applications of resorcinol in various preparations, the overall sensitizing potential, however, is low (Refs. 1 through 4).

(3) *Effectiveness.* The intrarectal application of a keratolytic can serve no useful purpose, and almost certainly will aggravate any existing disease because it will act as an irritant. Keratolytics exert a beneficial effect only when applied externally.

The Panel, therefore, concludes that resorcinol has no rational scientific basis for being included in OTC anorectal preparations for intrarectal use.

(4) *Evaluation.* Keratolytics have no reason to be used in intrarectal applications. There are no data to establish safety or effectiveness of resorcinol for intrarectal use and it is, therefore, placed in Category II.

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Category II Labeling

None.

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

Category III Active Ingredients

The Panel concludes that the available data are insufficient to permit final classification of the keratolytic active ingredients listed below. The Panel believes it is reasonable to provide 2 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed in OTC products:

Precipitated sulfur and sublimed sulfur (external use). The Panel concludes that precipitated sulfur and sublimed sulfur are safe for external use as a keratolytic at the proposed dosage, but there are insufficient data to prove effectiveness for use in OTC anorectal preparations.

(1) *Description.* (See part X. paragraph B.2.a(1) above—Description.)

(2) *Safety.* (See part X. paragraph B.2.a.(2) above—Safety.)

(3) *Effectiveness.* Sulfur has been used as a keratolytic agent in the treatment of acne but has not been shown to be effective in the treatment of anorectal disease (Ref. 1). Although no studies pertaining to the usefulness of sulfur in anorectal products were found, the Panel concludes that keratolytics demonstrated at other skin sites may apply here, although demonstration of this effect in safe doses is needed. Concentrations of sulfur at less than 0.1 percent in any vehicle are unlikely to be effective (Ref. 1).

(4) *Proposed dosage.* Adult external dosage is 2 to 10 mg per dosage unit and not to exceed six applications per 24 hours.

(5) *Labeling.* The Panel recommends the Category I labeling for keratolytic active ingredients. (See part X. paragraph B.1. above Category I Labeling.)

Reference

(1) Esplin, E. W., "Antiseptics and Disinfectants; Fungicides; Ectoparasiticides," *in* "The Pharmacological Basis of Therapeutics," 4th Ed., Edited by Goodman, L. S. and A. Gilman, The MacMillan Co., New York, pp. 1032–1066, 1970.

Category III Labeling

The Panel concludes that the available data are insufficient to permit final classification of the following claims. Additional data are required to support the following keratolytic claims:

a. "* * * but is keratolytic, softening the outer skin layers for more effective results."

b. "* * * for more effective results."

C. Data Required for Evaluation

The Panel has agreed that the protocols recommended in this document for the studies required to substantiate Category I are in keeping with the present state of the art and do not preclude the use of any advances or improved methodology in the future.

Principles in the design of an experimental protocol for testing keratolytic drug—a. *General principles.* Proof of keratolytic activity by an ingredient in the anorectal area would be difficult to demonstrate except by use of biopsy of the affected skin before and after use of the ingredient. Therefore, such testing may be performed on other body sites.

b. *Selection of patients.* Normal human volunteers or persons with hyperkeratotic conditions may be used to establish effectiveness of active ingredients.

c. *Methods of study.* The minimum number of visits should be the initial visit and a follow-up not more than 7 days. Double-blind studies on randomly selected patients should include the use of a fixed focus camera and a grading system.

d. *Interpretation of data.* Desquamation of tissue and necrosis of epithelial cells must be demonstrated within 7 days. Histological examination must give clear evidence of keratolysis.

XI. Anticholinergics

A. General Discussion

An anticholinergic is defined as a substance that inhibits or prevents the action of acetylcholine, the transmitter of cholinergic nerve impulses.

Anticholinergics produce their action systemically at ganglionic synapses, the endings of postganglionic parasympathetic nerves, the neuromuscular junction, and the central nervous system. There is no hypothetical or demonstrated evidence that anticholinergic agents have any role in the relief of anorectal symptoms. Drugs are preferred that limit their therapeutic effect to the particular site involved in the disorder under treatment; other actions constitute side effects. Anticholinergics have no proven controlled local or limited site of action without associated systemic effects.

The Panel finds that no claims were submitted for consideration that were attributed specifically to atropine (belladonna alkaloids). Further, the Panel concludes that anticholinergics as ingredients in OTC anorectal products are not generally recognized as safe and effective because of possible systemic toxicity resulting from unpredictable absorption, e.g., urinary retention, blurred vision, and dry mouth. No reports have been found to indicate that anticholinergics have any specific therapeutic local effects useful in treating anorectal symptoms.

The Panel concludes that any labeling, which is attributed to atropine (belladonna alkaloids and belladonna extract), is misleading and contains unacceptable claims for preparations used for the treatment of anorectal disorders.

B. Categorization of Data

1. *Category I conditions under which anticholinergic ingredients are generally recognized as safe and effective and are not misbranded.*

None.

2. *Category II conditions under which anticholinergic ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredient

The Panel has classified the following anticholinergic active ingredient as not generally recognized as safe and effective or as misbranded:

Atropine and belladonna extract (external and intrarectal use). The Panel concludes that atropine and belladonna extract are not safe or effective for use as anticholinergics in OTC anorectal preparations.

(1) *Description.* Atropine occurs as white crystals, usually needle-like, or as a white crystalline powder. Belladonna extract is obtained by extraction of belladonna leaf and contains in each 100 g not more than 1.5 g and not less than 1.35 g of the alkaloids of belladonna leaf (Ref. 1).

(2) *Safety.* No information regarding the toxicity of atropine (belladonna extract) following application to the anorectal area is available. Therefore, conclusions related to the ingredient must be extrapolated from related human use data. Systemic atropine poisoning may result from absorption of the alkaloid from broken or irritated skin (Refs. 2, 3, and 4). Poisoning due to belladonna plasters has been reported (Ref. 5). While there exists some difference of opinion regarding atropine's margin of safety, it is generally considered a potent and toxic drug (Refs. 6 and 7). The point has also been made that intoxication depends primarily on dose and individual susceptibility (Ref. 8).

Because atropine is a drug that requires individual adjustment of oral dosage levels by a physician, and systemic atropine poisoning may result due to the absorption of atropine when applied to the anorectal area, its use in OTC anorectal preparations is not safe.

(3) *Effectiveness.* The Panel has reviewed the literature extensively and can find no definitive clinical data to establish atropine and belladonna extract (belladonna alkaloids) as effective for use in the treatment of anorectal disorders. Nor were any data submitted to the Panel to support any claim for the use of atropine in anorectal disorders. It has no local effect on intact skin and its systemic effect, as described above for the class of anticholinergic ingredients, occurs only after absorption (Refs. 2, 3, and 4) from irritated or broken skin or mucous membranes when applied internally.

(4) *Evaluation.* The Panel concludes that atropine, because of its potent and toxic nature, the variability in response due to individual susceptibility, and no definitive clinical data supporting its effectiveness when applied externally or intrarectally, is not safe or effective for use in OTC anorectal preparations as an anticholinergic.

References

(1) "The National Formulary," 14th Ed., American Pharmaceutical Association, Washington, DC, pp. 56 and 58, 1975.

(2) Avidado, D. M., "Krantz and Carr's Pharmacologic Principles of Medical Practice," 8th Ed., The Williams and Wilkins Co., Baltimore, MD, p. 363, 1972.

(3) "AMA Drug Evaluations—1971," 1st Ed., American Medical Association, Chicago, IL, p. 586, 1971.

(4) Thienes, C. H. and T. J. Haley, "Clinical Toxicology," 5th Ed., Lea and Febiger, Philadelphia, PA, pp. 14–15, 1972.

(5) Sims, S. R., "Poisoning Due to Belladonna Plasters," *British Medical Journal*, 2:1531, 1954.

(6) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 4th Ed., The Macmillan Co., New York, p. 530, 1970.

(7) Gleason, M. N. et al., "Clinical Toxicology of Commercial Products. Acute Poisoning," The Williams and Wilkins Co., Baltimore, MD, pp. 34–36, 1969.

(8) Deichmann, W. D. and H. W. Gerarde, "Toxicology of Drugs and Chemicals," Academic Press, New York, p. 116, 1969.

Category II Labeling

None.

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* None.

XII. Miscellaneous Anorectal Ingredients

A. General Discussion

The actions of several ingredients reviewed by the Panel do not fall within the usual pharmacologic groups of local anesthetics, keratolytics, antiseptics, anticholinergics, vasoconstrictors, protectants, conterirritants, astringents, and wound-healing agents. However, these miscellaneous ingredients are found in OTC anorectal products and are discussed individually below.

B. Categorization of Data

1. *Category I conditions under which miscellaneous anprectal ingredients are generally recognized as safe and effective and are not misbranded.* None.

2. *Category II conditions under which miscellaneous anorectal ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC anorectal drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

Category II Active Ingredients

The Panel has classified the following miscellaneous anorectal active ingredients as not generally recognized as safe and effective or as misbranded:

Collinsonia extract (external and intrarectal use)

E. coli vaccines (external and intrarectal use)

Lappa extract (external and intrarectal use)

Leptandra extract (external and intrarectal use)

Mullein (external and intrarectal use)

a. Collinsonia extract (external and intrarectal use). The Panel concludes that there are no data to establish either the safety or effectiveness of collinsonia extract in OTC anorectal preparations.

(1) *Description.* Collinsonia consists of the dried root of *Collinsonia canadensi.* On analysis, collinsonia contains a resin, saponin, tannin, and mucilage (Refs. 1 and 2). No pharmacologic studies have been reported during the period 1960 to 1975 (Ref. 3).

(2) *Safety.* No data on either the safety or effectiveness of collinsonia have been found in any of the modern texts of pharmacology or in the literature for the past 15 years.

It has been used externally for wounds or as a gargle in the strength of 1 part of fluidextract to 3 parts of water. Used internally, 0.12 to 0.25 g was the accepted dose (Ref. 1). However, because no references were found referring to adverse effects, safety limits are impossible to determine. The presence of tannins introduces a potential danger. There are no reports available on anorectal use.

(3) *Effectiveness.* Collinsonia has been listed as an antispasmodic, diuretic, astringent, anticatarrhal, and diaphoretic used for dropsy, gravel, leukorrhea, cystitis, and inflammatory conditions of the genitourinary organs (Ref. 2). Older herbal medical books describe its use for lochial colic; snake bites; rheumatism; dumb ague; as a vulnerary for dropsy; as a poultice for bruises, sores, blows, falls, wounds, sprains, contusions; taken like tea for headaches, colics, cramps, dropsy, indigestion, bladder pains, ascites, and dropsy of the ovaries; as a powerful tonic in putrid and malignant fevers and in leukorrhea; and for chronic diseases of the respiratory tract, as an agent to relieve pulmonary irritation and a stimulant expectorant for irritation of the pneumogastric nerve (Ref. 4). It has been recommended as a cure for hemorrhoids when taken in oral doses of 1 to 2 drops of the tincture in water three or four times daily (Ref. 4).

The only evidence that would indicate that it is effective for use in anorectal disease consists of a few testimonials submitted in which it was used in combination with other ingredients (Ref. 4).

The disappearance of this ingredient from all modern texts and the fact that no new evidence has been presented concerning its effectiveness in the last 15 years are evidence that this is an outmoded form of treatment.

(4) *Evaluation.* The Panel concludes that there are no data to establish either the limits of safe application or any evidence of the effectiveness of collinsonia for use in anorectal preparations. It is therefore placed in Category II.

References

(1) "The Merck Index," 8th Ed., Merck and Co., Inc., Rahway, NJ, p. 279, 1968.

(2) "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, p. 319, 1976.

(3) OTC Volume 120057.

(4) OTC Volume 120053.

b. *E. coli vaccines (external and intrarectal use).* The Panel concludes that *E. coli* vaccines are not safe and effective for use in OTC anorectal preparations.

(1) *Description.* A milliliter of *E. coli* vaccine contains approximately 2,000,000,000 killed *E. coli* (Ref. 1). The method by which the bacteria are killed is not specified. The breakdown products are not specified except as metabolic and corpuscular elements, nor are the strains of *E. coli* employed in the preparation listed.

Preservation is secured by the addition of 2 percent liquefied phenol. However, the data concerning *E. coli* vaccines that have been presented to the Panel specify diluted vaccine so that only 0.4 percent of liquefied phenol is present (Ref. 1).

(2) *Safety.* Animal and human safety data that are available are sparse. Fifty rats were treated with *E. coli* vaccines placed into the wounds, and the tensile strength of these wounds were tested later; complication rates were identical with controls (Ref. 1).

Only two trials in humans have been reported; 40 patients in one trial and 54 patients in the other showed no evidence of local irritation (Ref. 1). Marketing data submitted by the company state that in 50 years the company producing this vaccine has never received nor heard of any reports of side effects (Ref. 1).

The Panel finds that these observations suggest that the product is safe, but are not extensive enough to warrant a firm conclusion.

(3) *Effectiveness.* To obtain a broader base for evaluating this ingredient, the Panel called in a consultant who was also a member of an Advisory Panel to the FDA, Bureau of Biologics (Ref. 2). This discussion incorporates his insight into the data as well as that of the Panel.

It is postulated by the manufacturer that the bacterial culture suspension breakdown products that are incorporated in the preparation act as local vaccines and induce immunologically mediated local resistance (i.e., stimulate the body's natural defenses in the anorectal area) against secondary infections that occur in anorectal disease. The Panel recognizes the need for the consumer to self-treat the limited symptoms of anorectal disorders such as burning, itching, pain, and swelling. If these symptoms persist beyond 7 days, a physician should be seen. It is the experience of the Panel that if secondary infection occurs, there is an important causative factor and may be of a serious nature that requires close supervision by the physician. Normal body defenses operate to prevent secondary infections in the presence of hemorrhoids or swollen tissue so that effectiveness studies would need to show a decrease in the number of infections occuring when compared to normal body defense mechanisms.

In the reports available, the effectiveness of *E. coli* vaccines cannot be separated from other components in the combination that apparently has been used in all experiments.

Evidence of effectiveness presented by the manufacturer includes the following animal experiments. In the first, rabbits were hypo-immunized against *E. coli* by subcutaneous injection of vaccine. After later subjecting the animals to a challenge by painting *E. coli* on the skin, serum titers became higher in the animals who had the injections (Ref. 1). The interpretation was that a measure of immunity could be obtained by painting lyophilized vaccine on intact skin. In another experiment, oral administration of lyophilized vaccine of inactivated *Salmonella typhi murium* protected mice against later oral administration of virulent *S. typhi murium* (Ref. 1). No evidence has been presented that *E. coli* vaccines applied intrarectally will increase the antiboyd titer to *E. coli.*

E. coli includes a large number of organisms that are classified in three large groups. Ewing (Ref. 3) states that 149 O antigens, 91 K antigens, and 51 H antigens are now known. Specific antigens for a number of these groups can be prepared. Oral administration of two strains of live *E. coli* have been reported to increase antibodies to these strains and also to *H. influenza* in adult volunteers (Ref. 4). However, the extent of cross reactivity to other strains of *E. coli* is not clear. furthermore, Sanford has presented data to the Panel (Ref. 2) that American investigators have not been able to effect immunization against *Salmonella* organisms.

No evidence is supplied to indicate that any immunity, if secured for *E. coli*, would be exerted preferentially in the anorectal area. Furthermore, even if *E. coli* could be removed from the fecal stream, even more serious

microorganisms might colonize the gut and affect the anorectal area.

Two clinical trials were reported with a compound containing *E. coli* vaccines (Ref. 1). In the first, 24 patients were treated with an ointment and 28 with a placebo that consisted only of the vehicle (Ref. 1). This report of a trial carried out in Japan noted that the best results were secured with patients with "hemorrodial knots" or "tears in anus." These entities probably should be interpreted as thrombosed hemorrhoids or anal fissures. A second trial was carried out in 40 patients (Ref. 1). In both reports a slight advantage was shown in overall improvement from the use of the vaccines compared with the vehicle itself. However, whether or not the control vehicle contained all substances except *E. coli* breakdown products is not clear.

There are other questions about the effectiveness of *E. coli* vaccines used in these investigations. There is no description of the method by which the organisms are killed; this undoubtedly would affect antigenicity. The preservatives in the combination used may not only influence antibacterial activity but also antigenicity. Metabolic and corpuscular elements, the breakdown products of *E. coli*, in the vaccines are not specified. The strains of *E. coli* are not specified, nor is there any indication as to whether or not the vaccine contains a K antigen. it is stated that the product has not been changed since 1922; this may mean a stock culture has been used, but this is not clear in the data (Ref. 1).

In conclusion, there are no studies available to show the relationship of infection to hemorrhodial symptoms that are amenable to treatment with ingredients approved by this Panel. Nor are there any studies to show that *E. coli* vacine can reduce irritation or pruritis by virtue of its purported immunologic effect. There is some evidence that ingestion or local application of *E. coli* vaccines can induce serum antibodies to *E. coli*, though it is not certain that this applies to other gram-negative bacteria such as *Salmonella*. There is no proof that this increase could be of any substantial quantitative effect insofar as destruction of *E. coli* in the body is concerned. Furthermore, there is the possibility that vaccines, if effective, might indeed be harmful because of other bacteria that would colonize the feces and affect the anorectal area. The data submitted from clinical trials are not adequate to establish general recognition of its effectiveness.

The Panel recognizes some of the claims associated with this ingredient as being effects that are useful in the treatment of anorectal symptoms for relief of irritation and/or pruritus, but believes that immunotherapy, the mechanism by which the claim for relief of infection is inferred, is such a complex process that any preparation claiming effectiveness on such a basis requires further testing before being included in OTC drug products.

A preparation presented to the Panel listed the active ingredients contained in a 1 g suppository as follows: Sterilized conserved metabolites and the corpuscular components of approximately 300 million coli-bacterials of different types (Ref. 1). The following were listed but are considered by the Panel as pharmaceutical aids: Liquefied phenol, neutral oil, adeps solidus, and cialit. Cialit is the sodium salt of 2-(ethylmercurithio)-5-benzoxazol-carboxylic acid. One g of ointment contains sterilized, conserved metabolites and the corpuscular components of approximately 330,000,000 coli-bacterials. The following were listed but are considered by the Panel as pharmaceutical aids: Petrolatum, hydrated lanolin, and amphocerin E (dehydag). No data concerning the safety or effectiveness of cialit or amphocerin E have been submitted. It is impossible from the material presented to separate the effectiveness of *E. coli* vaccines from other components in the combination. While it is considered that these agents act as preservatives or as vehicles and as such are outside the charge of the Panel, the Panel recommends that further information to be reviewed by another Panel is necessary concerning their composition and action.

(4) *Evaluation.* The Panel concludes that the safety and effectiveness of *E. coli* vaccines to relieve irritation, prevent infection, or relieve pruritus in the anorectal area are unproven. In view of the hazards that could result from unbalancing the bacterial flora of the anorectal area, *E. coli* vaccines are not safe and effective for use in anorectal preparations.

References

(1) OTC Volume 120030.

(2) Minutes of the OTC Panel on Hemorrhoidal Drug Products, 16th meeting, September 8 and 9, 1975.

(3) Ewing, W. H., "Enterobacteriaceae Infections," *in* "Diagnostic Procedures for Bacterial, Mycotic and Parasitic Infections," 5th Ed., Edited by Bodily, H. and E. Updike, American Public Health Association, Inc., New York, pp. 227–280, 1970.

(4) Schneerson, R. and J. B. Robbins, "Induction of Serum Haemophilus Influenzae Type B Capsular Antibodies in Adult Volunteers Fed Cross-Reacting Escherichia Coli 075:K100:H5," *New England Journal of Medicine*, 292:1083–1096, 1975.

c. Lappa extract (external and intrarectal use). The Panel concludes that there are no data to establish either the safety or effectiveness of lappa extract in OTC anorectal preparations.

(1) *Description.* Lappa consists of the dried root of *Arctium lappa*. It contains a volatile oil, a bitter principle, inulin, and tannin (Refs. 1 and 2).

The roots of *Arctium lappa* or of *A. minus* were recognized in several editions of standard pharmaceutical references (Refs. 1 and 2). The fluidextract was the preparation of choice. A proprietary product, burdock root oil, was a perfumed mixture of an alcoholic extract of the root with castor oil. These preparations and a poultice prepared from the fresh leaves were used in the treatment of various skin disorders such as psoriasis, prurigo (persistent itching eruptions of papules), and acne. The fluidextract, prepared from the dried root, was prescribed for internal administration in the management of gouty and rheumatic conditions (Ref. 3).

Considerable phytochemical work has been done on the root. Arctium is a reputed narcotic glycoside, but the chemical character of this compound has not been described (Ref. 4). Suchy et al. (Ref. 5) described arctiopicrin, a sesquiterpene lactone, but pharmacological properties have not been described. A substance, arctigenin, is a compound chemically resembling picropodophyllin, but its pharmacological resemblance has not been noted. Arctic acid is a new sulfur-containing acetylenic compound but is without proven pharmacological activity (Ref. 6).

(2) *Safety.* A search of the medical literature of the past 20 years produced no studies on either the safety or effectiveness of lappa. It is essentially a relic of old herbal medicine. One reference states that it was formerly used in the form of a decoction (1 in 20) and as a diuretic and diaphoretic with up to 500 mL being administered daily. The internal dose was given as 1 to 6 g (Ref. 1). Lappa was formerly used for dermatoses (Ref. 2). Claims made for the product published in 1930 were as an aperaitif, diuretic, diaphoretic, and ulcerative (Ref. 7). Externally it was also used for swelling, hemorrhoids, burns, and a hair grower, as an antisyphilitic, antirheumatic, and in large doses as a purgative (Ref. 7). As a purgative, 1 to 6 g of the root has been given with an average dose of 2 g (Ref. 7).

From these reports it would appear that because the oral administration of

lappa has been used in the past, external or intrarectal application would be safe within the limits of practical application, but there are no data to support either the lower or upper limits for this purpose. No reports on the safe application to anorectal disease were found.

(3) *Effectiveness.* From the composition of the root it would suggest that tannins are one of the active ingredients and that these ingredients could act as a mild astringent. An extract of the root has been found to lower blood sugar in rats, but this action has not been verified in other species and it was not quantified in the studies in rats (Ref. 8). Anorectal use of lappa is not currently mentioned in any of the standard pharmacology texts. With the exception of a few testimonials from patients who had used lappa in a combination, no data to support its effectiveness in anorectal disease could be found (Ref. 3).

(4) *Evaluation.* The Panel concludes there are no data to establish a minimum or maximum dose for lappa when contained in anorectal preparations. Safety has not been established, and there is no evidence that could be found to prove its effectiveness in anorectal preparations. This ingredient is therefore placed in Category II.

References

(1) "Martindale. The Extra Pharmacopoeia," 26th Ed., Edited by Blacow, N.W., The Pharmaceutical Press, London, England, p. 2021, 1972.

(2) "The Merck Index," 8th Ed., Merck and Co., Inc., Rahway, NJ, p. 609, 1968.

(3) OTC Volume 120053.

(4) Onaki, T., "Constituents of the Seeds of the Burdock (*Arctium lappa* L.). IV. Racemization of Arctigenin and Its Derivatives," *Journal of the Pharmaceutical Society of Japan*, 57:269–274, 1937.

(5) Suchy, M. et al., "Terpenes. LXXXIV. The Structure of Arctiopicrin, a Sesquiterpene Lactone from *Arctuim minus* Bernh," *Croatica Chemica Acta, 29:247–254, 1957.*

(6) Obata, S., M. Yoshikura and R. Washino, "Components of *Arctium lappa*," *Nippon Nogei Kagaku Kaishi*, 44:437–446, 1970.

(7) "The Merck Index," 4th Ed., Merck and Co., Inc., Rahway, NJ, p. 293, 1930.

(8) Lapynina, L. A. and T. F. Sysoeva, "Research on Some Plants to Determine Their Sugar-Lowering Properties," *Farmatsevtichnii Zhurnal (Kiev)*, 19:52–58, 1964.

d. Leptandra extract (external and intrarectal use). The Panel concludes that leptandra extract is probably safe but there is no proof of its effectiveness in anorectal preparations.

(1) *Description.* Leptandra is formed from the dried rhizome and roots of *L. virginica*, a North American plant. It contains on analysis a starch, esters of cinnamic acid, methaquinones, fatty acids, resins, saponins, tannin, and sugars (Ref. 1). It formerly was recognized in a standard pharmaceutical compendia (Ref. 2).

(2) *Safety.* It probably would be safe in an anorectal preparation because the oral dose of 1 to 4 g of the powder was employed in the past (Ref. 3). However, no safety data for external or intrarectal use have been found.

(3) *Effectiveness.* Leptandra in the form of the powdered dry drug, extract, or freshly gathered drug, was employed in the past as a cathartic in a dosage of 1 to 4 g (Ref. 3). It was believed to also aid as a cholagogue. This action was proved in dogs; an infusion increased total bile output and total cholate production in dogs (Ref. 4). The literature of 1960 to 1975 does not provide other pharmacologic data (Ref. 2).

The use of this ingredient has disappeared from the pharmacologic and pharmaceutic literature. Older texts regard it as a purgative, emetic, cholagogue, alterative, and tonic used for constipation, liver diseases, diarrhea, dysentery, and torpid liver (Ref. 5).

No data are available to indicate that it is effective in anorectal preparations.

(4) *Evaluation.* The Panel concludes that, although leptandra probably is safe for use in anorectal preparations, there is no evidence that it is effective. It is therefore placed in Category II.

References

(1) "The Merck Index," 7th Ed., Merck and Co., Inc., Rahway, NJ, p. 606, 1960.

(2) OTC Voume 120057.

(3) "The Dispensatory of the United States of America," 25th Ed., Edited by Osol, A. and G. E. Farrar, Jr., J. B. Lippincott Co., Philadelphia, PA, pp. 1735–1736, 1955.

(4) Petrovskii, G. A. et al, "The Cholagogic Effect of *Bupleurum exaltatum, Agrimonia asiatica, Leontopodium ochroleucum*, and *Veronica virginica*," *Farmacologiia i Toksikologiia*, 20:75–77, 1957.

(5) "The Merck Index," 4th Ed., Merck and Co., Inc., Rahway, NJ, 1930.

e. *Mullein (external and intrarectal use).* The Panel concludes that mullein is not safe or effective for use in OTC anorectal preparations.

(1) *Description.* Mullein (verbascum, great mullein, mullein dock) is a common weed native to Europe and to the United States. This drug is a carryover from folklore (Ref. 1).

Mullein is considered a demulcent, a soothing, bland substance. Because the Panel has not recognized any beneficial pharmacologic or therapeutic classification of demulcents for use in anorectal disorders, mullein is being considered independently.

(2) *Safety.* No acceptable or satisfactory scientifc data relevant to the safety of mullein for anorectal use was found. Fat droplets from *Verbascum orientale* were shown to contain an appreciable amount of carotenoids. Severe irritation to tissues where applied is known to occur (Ref. 2).

(3) *Effectiveness.* No evidence that mullein possesses any effectiveness in the treatment of anorectal disorders has been found. Mullein was formerly used in various pectoral complaints and locally applied to inflammation of mucous membranes without rational basis (Ref. 3). Mullein leaves are mucilaginous and are known to contain several saponins but probably in too small quantities to be physiologically important. It is theoretically possible that some therapeutic properties from tannins, flavonoids, or carotenoids (Ref. 4) exist but there are no clinical studies to support any such claim. It is improbable that mullein possesses any significant therapeutic virtues other than that of a demulcent (Ref. 5). Early Californians used mullein externally in pulmonary diseases and sprains. Spanish New Mexicans say that besides being pleasurable, inhaled smoke from cigarettes containing dried mullein leaves is good for asthma, and mullein leaves soaked in "mula blanca" (local corn whiskey) make a beverage that is also beneficial in counteracting the same complaint (Ref. 6).

(4) *Evaluation.* The Panel concludes that there are no data to establish a minimum or maximum dose for mullein applied to anorectal preparations. Nor is there evidence to prove the safety and effectiveness of this ingredient in OTC anorectal products. Therefore, mullein is placed in Category II.

References

(1) "The Dispensatory of the United States of America," 25th Ed., Edited by Osol, A. and G. E. Farrar, Jr., J. B. Lippincott, Co., Philadelphia, PA, pp. 1927–1928, 1955.

(2) Groger, D. and P. Simchen, "Zur Kenntnes Iridoider Pflanzenstoffe," *Die Pharmazie*, 22:315–321, 1967.

(3) Parker, K. D., "Rapid Gas Chromatographic Method for Screening of Toxicological Extracts from Alkaloids," *Annals of Chemistry*, 53:356, 1963.

(4) Pastowowy, A., *Acta Polon Pharmacology*, 2:287, 1938.

(5) Archiv Pharmacy, Verlog Chemie, W. Germany, 275, p. 145, 1937.

(6) Curtain, L. S. M., "Herbs of the Upper Rio Grande," Southwest Museum, Los Angeles, CA, p. 166, 1976.

Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of anorectal drug products are unsupported by scientific data and in some instances by sound theoretical reasoning.

The Panel considers the following claims to be misleading and unsupported by scientific data.

a. "Promotes healing."

b. "Astringent."

c. "Reduces swelling."

d. "An astringent to help reduce swollen tissues."

e. "For a mild local astringent, cooling, soothing and hygienic effect."

f. "Relief without the use of narcotics or astringents of any kind."

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.*

None.

The agency has carefully considered the potential environmental impacts of this proposal and has concluded that the action will not have a significant effect on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting this finding contained in an environmental assessment (pursuant to 21 CFR 25.31, proposed December 11, 1979, 44 FR 71742) may be seen in the Office of the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 346, to read as follows:

PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—[Reserved]

Subpart D—Labeling

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—General Provisions

§ 346.1 Scope.

An over-the-counter anorectal drug product in a form suitable for external (topical) or intrarectal (rectal) administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this Part 346 in addition to each of the general conditions established in § 330.1 of this chapter.

§ 346.3 Definitions.

(a) *Anorectal drug.* An agent that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas.

(b) *Local anesthetic drug.* An agent that produces local disappearance of pain, buring, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations.

(c) *Vasoconstrictor drug.* An agent that causes temporary constriction of blood vessels.

(d) *Protectant drug.* An agent that provides a physical barrier, forming a protective coating over skin or mucous membranes.

(e) *Counterirritant drug.* An agent that produces a local sensation that distracts from the perception of pain, buring, or itching.

(f) *Astringent drug.* An agent that is applied to the skin or mucous membranes for a local and limited protein coagulant effect.

(g) *Keratolytic drug.* An agent that causes desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis.

(h) *External use.* Topical application of an anorectal product to the skin of the perianal area and/or the skin of the anal canal.

(i) *Intrarectal use.* Topical application of an anorectal product to the mucous membrane of the rectum.

Subpart B—Active Ingredients

§ 346.10 Local anesthetic active ingredients.

The active ingredients of the product consist of the following when used within the dosage limits established for each ingredient:

(a) Benzocaine 5 to 20 percent in polyethylene glycol ointment.

(b) Pramoxine hydrochloride 1 percent in a cream or jelly formulation.

(1) *For cream formulation.* Pramoxine hydrochloride 1 percent in a cream base containing methylparaben USP, propylparaben USP, cetyl alcohol NF, synthetic spermaceti NF, sodium lauryl sulfate USP, glycerin USP, and purified water USP.

(2) *For jelly formulation.* Pramoxine hydrochloride 1 percent in a jelly base containing propylene glycol USP, hydroxypropyl methylcellulose USP (4000 centipoises), and purified water USP.

§ 346.12 Vasoconstrictor active ingredients.

The active ingredients of the product consist of the following when used within the dosage limits established for each ingredient:

(a) Ephedrine sulfate 2 to 25 milligrams in aqueous solution per dosage unit.

(b) Epinephrine hydrochloride 100 to 200 micrograms in aqueous solution per dosage unit.

(c) Phenylephrine hydrochloride 0.5 milligram in aqueous solution per dosage unit.

§ 346.14 Protectant active ingredients.

The Active ingredients of the product consist of the following when used within the dosage limits established for each ingredient:

(a) Aluminum hydroxide gel 50 percent or greater per dosage unit.

(b) Calamine 5 to 25 percent (based on the zinc oxide content of calamine per dosage unit.

(c) Cocoa butter 50 percent or greater per dosage unit.

(d) Cod liver oil 50 percent or greater per dosage unit.

(e) Gylcerin 50 percent or greater of a 20 to 45 percent solution of glycerin in water per dosage unit.

(f) Kaolin 50 percent or greater per dosage unit.

(g) Lanolin 50 percent or greater per dosage unit.

(h) Mineral oil USP 50 percent or greater per dosage unit.

(i) Shark liver oil 50 percent or greater per dosage unit.

(j) Starch 50 percent or greater per dosage unit.

(k) White petrolatum USP 50 percent or greater per dosage unit.

(l) Wool alcohols 4 to 7 percent per dosage unit.

(m) Zinc oxide 5 to 25 percent per dosage unit.

§ 346.16 Counterirritant active ingredients.

The active ingredient of the product consists of the following when used within the dosage limits established for each ingredient:

(a) Menthol 0.25 to 1.0 percent in aqueous solution.

§ 346.18 Astringent active ingredients.

The active ingredients of the product consist of the following when used within the dosage limit established for each ingredient:

(a) Calamine 5 to 25 percent (based on the zinc oxide content of calamine percent dosage unit.

(b) Witch hazel water 10 to 50 percent per dosage unit.

(c) Zinc oxide 5 to 25 percent per dosage unit.

§ 346.20 Keratolytic active ingredients.

The active ingredients of the product consist of the following when used within the dosage limit established for each ingredient:

(a) Alcloxa 0.2 to 2.0 percent per dosage unit.

(b) Resorcinol 1 to 3 per dosage unit.

§ 346.22 Permitted combinations of active ingredients.

Two but not more than four protectant ingredients identified in § 346.14 may be combined.

Subpart C—[Reserved]

Subpart D—Labeling

§ 346.50 General labeling of anorectal drug products.

The following labeling is applicable as general labeling for anorectal products as well as labeling for specific anorectal ingredients identified in §§ 346.52, 346.54, 346.56, 346.58, 346.60, and 346.62:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or "anorectal product."

(b) *Indications.* The general labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) "For the temporary relief of discomfort of (when the product is intended for use on concurrent symptoms, the symptoms must be specified) associated with hemorrhoids and other anorectal disorders."

(2) "For the temporary relief of the discomfort associated with hemorrhoids and other anorectal disorders."

(3) "For the temporary relief of itching associated with hemorrhoids and other anorectal disorders."

(4) "For the temporary relief of anorectal itching."

(5) "For the temporary relief of local itching associated with inflamed hemorrhoidal tissues."

(6) "For the temporary relief from the itching and discomfort associated with hemorrhoids and other anorectal disorders."

(7) "For the temporary relief of the discomforts associated with piles (hormorrhoids) and other anorectal disorders."

(8) "For the temporary relief of symptoms of anorectal disorders."

(9) "Gives temporary relief of anorectal itching."

(10) "Temporary relief of itching discomfort associated with hemorrhoids and other anorectal disorders."

(11) "For the temporary relief of symptoms associated with hemorrhoids and other anorectal disorders."

(12) "To temporarily soothe local discomfort associated with hemorrhoids and other anorectal disorders."

(13) "To help relieve the discomfort associated with hemorrhoids and other anorectal disorders."

(14) "For the temporary relief of itching."

(15) "For the temporary relief of symptoms of inflammation associated with hemorrhoidal tissues."

(16) "Gives temporary relief of discomfort due to external hemorrhoids and other anorectal disorders."

(17) "For the temporary relief of pruritus ani."

(c) *Warnings.* Warning statements may be combined to eliminate the duplication of words or phrases, but the combined warning statement must be clear and understandable with no decrease in meaning and emphasis. Warning statements must be included on the immediate product container and the package in a 'box border'; they should be printed in black ink or in the color of the most prominent type appearing on either the container or the package, that is, in such a fashion that the prominence and meaning of the warning is not obscured. Appropriate use of printing techniques, styles, colors, and illustration should be utilized to aid the consumer in encountering and understanding the important meaning of the labeling. Warning or caution statements should be typeset in no less than eight-point type, or one-third the point size of the largest type face appearing on both the container and labeling, whichever is larger. The general labeling of the product contains the following general warnings under the heading "Warnings";

(1) "If symptoms do not improve, do not use this product for more than 7 days and consult a physician."

(2) "Do not exceed the recommended daily dosage except under the advice and supervision of a physician."

(3) "If itching persists for more than 7 days, consult a physician."

(4) "In case of bleeding, consult a physician promptly."

(5) *For anorectal products containing perfume.* "If redness, burning, itching, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician."

(6) *For products for external use—For products that are ointments, creams, jellies, foams, pads, or gels for external use only.* "Do not put this product into the rectum by using fingers or any mechanical device or applicator."

(7) *For products for intrarectal use—*

(i) *For all anorectal products for intrarectal use by insertion into the rectum, except ingredients identified in § 346.14.* "The safety of this product has not been established for use by pregnant women or by nursing mothers."

(ii) *For products that are to be used with special applicators such as pile pipes or other mechanical device.* "Do not use this product if the introduction into the rectum causes additional pain. Consult a physician promptly."

(iii) *For anorectal products that contain at least one anorectal ingredient identified in §§ 346.10, 346.12, 346.16, or 346.20 other than a protectant or astringent anorectal ingredient identified in §§ 346.14 and 346.18.* "Do not use this product in children under 12 years of age except under the advice and supervision of a physician."

(d) *Directions.* Many anorectal products may be used externally as well as intrarectally. Whenever a product is for both external and intrarectal use, the labeling of the product contains a clear separation of each set of directions under the headings, "For external use" and "For intrarectal use." The general labeling of the product contains the following statements or information under the required heading "Directions," followed by "or as directed by a physician."

(1) *For all products.* Recommended or usual dosage, frequency of

administration (e.g., every 4 hours, three times daily), and site of administration (i.e., external or intrarectal application).

(2) *For all products.* "When practical, wash the anorectal area with mild soap and warm water and rinse off all soap before application of this product."

(3) *For products for external use which are ointments, pastes, creams, jellies, foams, or gels.* "Apply externally to the anorectal area."

(4) *For products for external use which are pads containing anorectal ingredients.* "Gently apply by patting and then discard."

(5) *For products for external use which are ointments, pastes, creams, jellies, foams, pads, or gels for external use only.* "For external use only."

(6) *For products for intrarectal use which are wrapped suppositories for insertion into the rectum.* "Remove wrapper before inserting into the rectum."

(7) *For all products for intrarectal use to be inserted into the rectum.* "For use by insertion into the rectum."

(8) *For products for intrarectal use which are to be used with special applicators such as pile pipes or other mechanical devices.* "Gently insert applicator into the rectum."

§ 346.52 Labeling of local anesthetic drug products.

The labeling of the product contains the following information as well as any applicable general labeling identified in § 346.50:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or as an "anorectal product."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases for any ingredient identified in § 346.10:

(1) "For the temporary relief of pain."

(2) "For the temporary relief of itching."

(3) "For the temporary relief of burning."

(4) "For the temporary relief of the discomforts of hemorrhoids (piles) or other anorectal disorders."

(5) "For the temporary relief of itching, burning, and soreness of hemorrhoids or other anorectal disorders."

(6) "For the temporary relief of pain and itching of hemorrhoidal tissue or other anorectal disorders."

(7) "For the temporary relief of itching, burning, and pain associated with hemorrhoids or other anorectal disorders."

(8) "For the temporary symptomatic relief of pain, itch, burning, and soreness of some types of hemorrhoids or other anorectal disorders."

(9) "For the temporary relief of pain and itching due to painful hemorrhoids or other anorectal disorders."

(10) "For the temporary relief of pain and itching of hemorrhoids and other anorectal disorders."

(11) "Temporarily helps numb pain associated with hemorrhoids."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings": *For products containing any ingredient identified in § 346.10.* (1) *"Caution:* Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician."

(2) *"Caution:* This product is for external use only. Do not apply inside the rectum in any way."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as directed by a physician."

(1) *For products containing benzocaine identified in § 346.10(a).* Adult external dosage is 5 to 20 percent benzocaine per dosage unit in polyethylene glycol ointment up to six times daily and not to exceed 2.4 grams per 24 hours.

(2) *For products containing pramoxine hydrochloride identified in § 346.10(b).* Adult external dosage is 1 percent pramoxine hydrochloride in a cream or jelly formulation up to five times daily and not to exceed 100 milligrams per 24 hours.

§ 346.54 Labeling of vasoconstrictor drug products.

The labeling of the product contains the following information as well as any applicable general labeling identified in § 346.50:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or as an "anorectal product."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases for any ingredient identified in § 346.12:

(1) "Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders."

(2) "Temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders."

(3) "Temporarily shrinks hemorrhoidal tissue."

(c) *Warnings.* The labeling of the product contains the following warning under the heading "Warning": *For products containing any ingredient identified in § 346.12.* "Do not use this product if you have heart disease, high blood pressure, hyperthyroidism, diabetes, difficulty in urination, or are taking tranquilizers or nerve pills."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as directed by a physician."

(1) *For products containing ephedrine sulfate identified in § 346.12(a).* Adult external and intrarectal dosage is 2 to 25 milligrams ephedrine sulfate in aqueous solution per dosage unit up to four times daily and not to exceed 100 milligrams per 24 hours.

(2) *For products containing epinephrine hydrochloride identified in § 346.12(b).* Adult external dosage is 100 to 200 micrograms epinephrine hydrochloride in aqueous solution per dosage unit up to four times daily and not to exceed 800 micrograms per 24 hours.

(3) *For products containing phenylephrine hydrochloride identified in § 346.12(c).* Adult external and intrarectal dosage is 0.5 milligram phenylephrine hydrochloride in aqueous solution per dosage unit up to four times daily and not to exceed 2 milligrams per 24 hours.

§ 346.56 Labeling of protectant drug products.

The labeling of the product contains the following information as well as any applicable general labeling identified in § 346.50:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or as an "anorectal product."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases for ingredients identified in § 346.14 (b through e) and (g through m):

(1) "Forms a protective coating over inflamed tissues which can relieve itching."

(2) "Aids in the relief of itching or anorectal discomfort."

(3) "Temporarily forms a protective coating over inflamed tissues which helps prevent drying of tissues."

(4) "Temporarily protects irritated areas from irritating materials."

(5) "Temporarily relieves anorectal itching."

(6) "Temporarily relieves burning."

(7) "Provides temporary relief from skin irritations."

(8) "For the temporary relief of itching associated with hemorrhoids, inflamed hemorrhoidal tissue or other anorectal disorders."

(9) "For the temporary relief of local itching associated with hemorrhoids, inflamed hemorrhoidal tissues, or other anorectal disorders."

(10) "For the temporary relief from the itching and discomfort due to hemorrhoids or other anorectal disorders."

(11) "Temporarily provides a bland, soothing coating for relief of anorectal discomforts."

(12) "Temporarily provides lubrication in the anorectal area."

(13) "Temporarily lubricates and protects the inflamed irritated anorectal surface to help make bowel movements less painful."

(14) "Temporarily protects from irritation and abrasion during bowel movement."

(15) "Temporarily helps soften and lubricate dry inflamed perianal skin."

(16) "Temporarily relieves the symptoms of perianal skin irritation, and itching."

(17) "Provides lubrication and may help make bowel movements more comfortable."

(18) *For products containing alumina gel identified in § 346.14(a) and for products containing kaolin identified in § 346.14(f).* (i) "For the temporary relief of itching associated with moist anorectal conditions."

(ii) "Temporarily protects irritated areas from irritating materials."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing alumina gel identified in § 346.14(a) and for products containing kaolin identified in § 346.14(f).* "Remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area."

(2) *For products containing wool alcohols identified in § 346.14(l) when wool alcohols have been added to the final formulation as separate ingredient.* "*Caution:* Certain persons can develop allergic reactions to ingredients in this product. If redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as directed by a physician."

(1) *For products containing alumina gel identified in § 346.14(a).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(2) *For products containing calamine identified in § 346.14(b).* Adult external and intrarectal dosage is 5 to 25 percent per dosage unit (based on the zinc oxide content of calamine) and not to exceed six applications per 24 hours or after each bowel movement.

(3) *For products containing cocoa butter identified in § 346.14(c).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(4) *For products containing cod liver oil identified in § 346.14(d).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement and not to exceed 10,000 International Units vitamin A and 400 International Units vitamin D per 24 hours.

(5) *For products containing glycerin identified in § 346.14(e).* Adult external dosage is 20 to 45 percent glycerin in aqueous solution when used in concentrations of at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(6) *For products containing kaolin identified in § 346.14(f).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(7) *For products containing lanolin identified in § 346.14(g).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(8) *For products containing mineral oil identified in § 346.14(h).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(9) *For products containing shark liver oil identified in § 346.14(i).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement and not to exceed 10,000 International Units vitamin A and 400 International Units vitamin D per 24 hours.

(10) *For products containing starch identified in § 346.14(j).* Adult external and intrarectal dosage at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(11) *For products containing white petrolatum identified in § 346.14(k).* Adult external and intrarectal dosage is at least 50 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(12) *For products containing wool alcohols identified in § 346.14(l).* Adult external and intrarectal dosage is 4 to 7 percent per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(13) *For products containing zinc oxide identified in § 346.14(m).* Adult external and intrarectal dosage is 5 to 25 percent dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

§ 346.58 Labeling of counterirritant drug products.

The labeling of the product contains the following information as well as any applicable general labeling identified in § 346.50:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or as an "anorectal product."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases for any ingredient identified in § 346.16:

(1) *For all products.* (i) "For the temporary relief of itching or pain in the perianal area."

(ii) "Can help distract from pain or itch."

(iii) "Temporary relief of itch or pain in the perianal area."

(2) *For products containing menthol identified in § 346.16.* (i) "May provide a cooling sensation."

(ii) "Temporarily relieves itching and soothes burning."

(c) *Warning.* The labeling of the products contains the following warning under the heading "Warning": *For products containing menthol identified in § 346.16. "Caution:* Certain persons can develop allergic reactions to ingredients in this product. If redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as

directed by a physician." *For products containing menthol identified in § 346.16.* Adult external dosage is 0.25 to 2.0 percent per dosage unit in aqueous solution and not to exceed six applications per 24 hours.

§ 346.60 Labeling of astringent drug products.

The labeling of the product contains the following information as well as any applicable general labeling identified in § 346.50:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or as an "anorectal product."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases for any ingredient identified in § 346.18:

(1) "Aids in protecting irritated anorectal areas."

(2) "Temporary relief of irritation."

(3) "Temporary relief of itching."

(4) "Temporary relief of burning."

(5) "Temporarily relieves itching and soothes burning."

(6) "Temporarily relieves discomfort."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings": General warnings under § 346.50(c) apply.

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as directed by a physician."

(1) *For products containing calamine identified in § 346.18(a).* Adult external and intrarectal dosage in 5 to 25 percent calamine per dosage unit (based on the zinc oxide content of calamine) and not to exceed 6 applications per 24 hours or after each bowel movement.

(2) *For products containing witch hazel water identified in § 346.18(b).* Adult external dosage in 10 to 50 percent witch hazel water per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

(3) *For product containing zinc oxide identified in § 346.18(c).* Adult external and intrarectal dosage is 5 to 25 percent zinc oxide per dosage unit and not to exceed six applications per 24 hours or after each bowel movement.

§ 346.62 Labeling of keratolytic drug products.

The labeling of the product contains the following information as well as any applicable general labeling identified in § 346.50:

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "anorectal agent" or as an "anorectal product."

(b) *Indications.* The labeling of the product contains the following statement of the indications under the heading "Indications" that is limited to the following phrase for any ingredient identified in § 346.20: "For the temporary relief of itching."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing resorcinol identified in § 346.20(b).*

(i) *"Caution:* Certain persons can develop allergic reactions to ingredients in this product. If redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a physician."

(ii) "Do not use in open wounds near the anus."

(2) [Reserved]

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as directed by a physician."

(1) *For products containing alcloxa identified in § 346.20(a).* Adult external dosage is 0.2 to 2.0 percent per dosage unit and not to exceed six applications per 24 hours.

(2) *For products containing resorcinol identified in § 346.20(b).* Adult external dosage is 1 to 3 percent per dosage unit and not to exceed six applications per 24 hours.

Interested persons are invited to submit their comments in writing (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before August 18, 1980. Such comments should be addressed to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a memorandum or brief. Comments replying to comments may also be submitted on or before September 24, 1980. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: May 13, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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Part III

Department of Housing and Urban Development

Office of the Assistant Secretary for Policy Development and Research

Final Rehabilitation Guidelines

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Policy Development and Research

[Docket No N-80-1003]

Final Rehabilitation Guidelines

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of final rehabilitation guidelines.

SUMMARY: HUD is hereby promulgating the final Rehabilitation Guidelines developed in accordance with Section 903 of Pub. L. 95-557, "Housing and Community Development Amendments of 1978." These Guidelines are intended for the voluntary adoption by States and communities to be used in conjunction with existing building codes by State and local officials in the inspection and approval of rehabilitated properties.

FOR FURTHER INFORMATION CONTACT: Robert J. Kapsch, Program Manager, Division of Energy, Building Technology and Standards, Room 8164, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410. Telephone (202) 755-8154. This is not a toll free number.

SUPPLEMENTARY INFORMATION: HUD published the draft Rehabilitation Guidelines in the Federal Register for public comment on November 5, 1979 (44 FR 63760). Thirty-four communications, containing 188 comments, were received. After careful consideration of the comments received, the draft Rehabilitation Guidelines were revised, in part. A summary of the major changes made to the Guidelines is published herein.

The draft Rehabilitation Guidelines published in the Federal Register on November 5, 1979 contained eight specific guidelines:

- Guideline for Setting and Adopting Standards for Building Rehabilitation
- Guideline for Municipal Approval of Building Rehabilitation
- Statutory Guideline for Building Rehabilitation
- Guideline for Managing Official Liability Associated With Building Rehabilitation
- Egress Guideline for Residential Rehabilitation
- Electrical Guideline for Residential Rehabilitation
- Plumbing Drain-Waste-Vent Guideline for Residential Rehabilitation
- Guideline for Fire Ratings of Archaic Materials and Assemblies
- Public comment was both general and specific in nature.

1. General Comments

Two comments were received that the guidelines were difficult to read and one comment was received that indicated that the guidelines would be difficult to use in the field. The format of the final guidelines has been reorganized to make the guidelines less complex and to improve their overall readability. As published, the guidelines will be in a format suitable for field use.

A number of commenters cited the need for supplemental information about issues not directly addressed in the guidelines. These included the following code-related rehabilitation problems: training of inspectors; structural and seismic safety; the need for more specific code equivalencies; accessibility for the handicapped; the liability of design professionals; energy conservation; state preemption of local codes; inclusion of additional technical and regulatory detail; and building department budgets. Most of these issues were previously considered by HUD for inclusion in the guidelines, but were not addressed either due to time and monetary constraints, or for state-of-the-art limitations or for other practical reasons. All of the issues mentioned will be considered by HUD for development as future guidelines.

Several comments were addressed to issues not related to the rehabilitation guidelines, such as the need for housing for the elderly, mobile home research, problems of lead based paint standards, and the general need for building codes and standards. Where possible, these comments were referred to those offices in HUD active in these areas.

Two commenters requested that the guidelines be tabled or delayed, citing the twelve month limitation imposed by Congress for the development of the guidelines as inadequate. Since the time schedule for promulgating these guidelines have been legislatively determined, HUD did not delay or table the promulgation of the final Rehabilitation Guidelines.

Two comments were received indicating the belief that the guidelines were a building code. Five other comments expressed concern that the guidelines either might be interpreted as a code or, at some time in the future, might be imposed as a code. Although the guidelines were clearly identified as such and were not published in code language, emphasis has been added to the final guidelines clarifying their function under Section 903 of the Act.

Two comments were received indicating that the guidelines did not contain a statement that their purpose was to promote rehabilitation. The final guidelines remedy this.

Two comments were received regarding recommended actions to be taken by HUD following the promulgation of the final guidelines. These included a recommendation to provide assistance in their use and to institute a mechanism to expand, revise and update the contents of the guidelines. Both comments will be considered by HUD in the development of future activities associated with these guidelines.

2. Specific Comments

Because of the technical nature of many of the comments received, HUD used the services of the National Institute of Building Sciences and selected nationally recognized experts to aid in evaluating each of the technical comments received and to provide their recommendations to HUD. The following is a description of the substantive modifications or revisions made to each of the eight individual guidelines.

a. Guideline for Setting and Adopting Standards for Building Rehabilitation: Fourteen commenters provided numerous comments directed at this guideline. In response to these comments, the following changes were made:

- The narrative on historic preservation was clarified in Part II, and a recommendation added in Part III dealing with the inclusion of historic preservation waiver clauses.
- A discussion of the approach to residential rehabilitation taken by the State of California was added to both the guideline and as Appendix 6;
- The description of San Francisco's approach to rehabilitation was amended in both the guideline and in Appendix 3.
- The description of Denver's approach to rehabilitation was amplified according to additional information received;
- A caveat to localities governed by statewide mandatory codes was added to the guideline;
- The discussion and diagrams related to the varying levels of performance discussed in Part I were clarified;
- A discussion of the scope of rehabilitation covered was added;
- Three of the four examples of retroactive provisions were deleted from the appendix as one example was considered sufficient;
- A modification was made to Appendix 10 adding a discussion on the use of live load placards;
- An additional appendix was added citing an article from the Southern

Building Magazine, February/March 1980, entitled, "Rehabilitation of Existing Building: An Achievable Goal"

Three comments were received to delete or limit the discussion of the 25/50 percent rule because of the deficiencies of this rule. HUD did not delete or limit the discussion of this rule as it is a major factor in most code jurisdictions and is being used to encourage rehabilitation in many of those jurisdictions.

Several comments were made criticizing the guideline's discussion of the changing levels of safety within and among building, housing, maintenance and hazard abatement codes; however, this discussion was considered essential to the guidelines and has been retained in essence.

The revised guideline together with Appendix 3, and the new Appendices 6 and 11 together with a bibliography are being reproduced in this notice.

b. Guideline for Approval of Building Rehabilitation: Two comments were received. The first brought Seattle's rehabilitation program to HUD's attention and the second stated that many building departments already follow these or similar procedures suggested in the guideline. Although there is no doubt that many building departments follow these or similar procedures, it is also known that many do not. HUD therefore is promulgating this guideline. However, for purposes of clarification, the guideline's format was reorganized to stress parallels between submittal, review and approval procedures for rehabilitation and those required for new construction. References were added to the guideline regarding Seattle's rehabilitation program and its field inspection procedure, and to Portland's Outreach program. The term "Municipal" was deleted from the title of the final guideline.

The full revised guideline is being reproduced in this notice.

c. Statutory Guideline for Building Rehabilitation: Two comments were received directed at this guideline. The first recommended that a definition of rehabilitation be added to the guideline. Although it is difficult to define rehabilitation, because many communities use the term in many different ways, a discussion of the scope of rehabilitation has been added to the *Guideline for Setting and Adopting Standards for Building Rehabilitation.* The second comment suggested an improved appeals procedure. A review of the subject indicated that there was little substantive difference between the suggested procedure and that described in the guideline. This guideline, therefore, has not been modified and will be adopted as published in the draft.

d. Guideline for Managing Official Liability Associated With Building Rehabilitation: Two comments were received. The first suggested that liability may not be a significant issue in building rehabilitation. The problem identification study undertaken as a part of the guidelines preparation indicated that official liability was viewed as a serious concern in rehabilitation projects by building officials throughout the country. No change, therefore, was made. The second suggested that the liability of designers of rehabilitation projects also be covered. HUD is reviewing this suggestion as part of its efforts in developing future guidelines. This guideline therefore has not been modified and is being adopted as published in draft.

e. Egress Guideline for Residential Rehabilitation. Eight commentors provided a number of comments directed toward this guideline. Based on the comments received and a thorough technical review resulting from these comments, the following changes were made:

- The assumptions upon which the guideline is based were restated and clarified, including:
  - the guideline is intended for use only by persons knowledgeable in fire protection and the principals of building construction;
  - the guideline stresses the retention of as many of the existing components of the egress system as possible, provided that they assure approximately equivalent levels of fire safety performance to that intended by existing codes;
  - the guideline is meant to apply whenever current code requirements are triggered;
  - the problem/solution statements shown in the guideline are meant to be representative and not exhaustive.
- A number of revisions were made to the text of each egress category, including:
  - a number of code intent statements were modified;
  - one problem/solution statement was eliminated since it was largely redundant;
  - one problem/solution statement was added, dealing with the adequacy of horizontal exits;
  - wherever the guideline recommends deviating from existing code requirements, the installation of single station smoke detectors has been made a part of the solution statement;
  - a number of references to the Uniform Building Code and its Appendix Chapter 12 were revised and corrected;
  - The guideline's format was substantially reorganized to accommodate the above revisions.

A recommendation to delete the problem/solution statement that conditionally allows the use of a single exit in a three story building was not adopted since an approximately equivalent level of fire safety to that required by existing codes was provided by the solution stated. A comment criticizing the guideline on reliance on automatic fire suppression systems and the use of domestic water supplies for sprinkler systems was considered, but the emphasis on these solutions was not changed since both can be used to provide approximately equivalent levels of fire safety to that required by existing codes.

The full revised guidelines is being republished in this notice.

f. Electrical Guidelines for Residential Rehabilitation: Seven commenters provided detailed comments directed to this guideline. Based on the comments received and a thorough technical review resulting from these comments, the following changes were made:

- The assumptions upon which the guideline is based were restated and clarified, including:
  - the guideline is intended for use only by persons knowledgeable in electrical installations:
  - the guideline stresses retention of as many of the existing components of the electrical system as possible, provided that they assure approximately equivalent levels of electrical safety performance to that intended by existing codes;
  - the guideline is meant to apply whenever current code requirements are triggered or may be used in determining alternate electrical rehabilitation standards.
- The inspection portion of the guideline was made more precise;
- The example in the problem/solution statement regarding the spacing of electrical outlets was deleted and replaced by examples from the BOCA and the City of Detroit codes;
- The apparent emphasis on the use of non-metalic cable was corrected to place equal emphasis on the use of metallic cable and conduit;
- Chapter 10 of the Detroit Electrical Code was added as an appendix to this guideline.

A recommendation that load tests be performed was not adopted because there currently are no reliable standard testing methods available. A

recommendation to disallow second service entrances was not adopted since the alternative of unprotected service wiring was considered more hazardous. A third comment, a recommendation to require wired-in smoke detectors was not adopted since current codes do not require it.

The full revised guideline is being republished in this notice.

g. Plumbing Drain-Waste-Vent (DWV) Guideline for Resdential Rehabilitation Five commenters provided comments directed toward this guideline.

Based on the comments received and a thorough technical review resulting from these comments, the following changes were made:

- The basis for the guideline was restated and clarified, inlcuding:
- its intended use only by qualified building professionals;
- its stress on retaining as many of the existing components of the plumbing DWV system as possible, provided that they assure approximately equivalent levels of health performance to that intended by existing codes;
- its applicability whenever current code requirements are triggered;
- The guideline was rearranged into three parts: (1) determination of existing conditions, (2) problems/solutions, and (3) appendices;
- The use of tests to determine functional performance was amplified;
- References to test data were clarified and expanded;
- Tabular information on the capacity of single stack systems was revised;
- References to several acceptable solutions described in Chapter 16 of Standard Building Code were added;
- Many of the illustrations in the guideline's appendix were clarified and revised;
- Performance criteria mentioned in one of the problem/solution statements were placed in an appendix to the guideline.
- The full revised guideline, with its appendix, is being republished in this notice.

h. Guideline on Fire Ratings of Archaic Materials and Assemblies: Six commenters provided comments directed toward this guideline. Based on the comments received, the following major changes were made:

- Several technical references or descriptions in the introductory text were modified, clarified, or expanded;
- Additional information was added in the introduction regarding Harmathy's second rule;
- The section on "Doors and Door Materials" in the introduction was revised to outline a procedure for technical evaluation, and a case study describing door modifications was added;
- Several minor corrections were made to the fire rating data listed in the appendix.

The use of British terminology, taken from British sources, in the fire rating data was critized. The British sources, however, were not deleted from the fire rating data since most fire experts regard this information as very reliable and not generally available elsewhere.

The guideline's revised introduction, including the section on "Doors and Door Materials," and the added case study on door modification, is being republished in this notice.

Accordingly, the draft Rehabilitation Guidelines published for comment on November 5, 1979 are adopted with the following changes:

Guidelines as Published 44 FR 63760

Page	Column	Line	Changes
●Guideline for setting adopting standards.			Guideline published in this notice replaces draft guideline.
63764	1	First	
●Appendix 1 to above guideline			Deleted.
63802	1	First	
Appendix 2 to above guideline			Deleted.
63809	1	First	
Appendix 3 to above guideline			Deleted.
63812	1	First	
Appendix 7 to above guideline			Modified, renumbered to Appendix 3 and republished in this notice.
63848	1	First	
(Not included in draft guideline.)			Appendix 6 added and published in this notice, "State of California Rehabilitation and Repair of Existing Buildings."
(Not included in draft guideline)			Appendix 11 added and published in this notice, "Rehabilitation of Existing Buildings: An Achievable Goal, reprint from Southern Building Magazine.
●Guideline for municipal approval of building rehabilitation.			Guideline published in this notice replaces draft guideline. "Municipal" deleted from title.
63790	1	First	
●Statutory guideline for building rehabilitation.			Guideline has not been modified and will be adopted as published in the draft.
63793		First	
●Guideline for managing official liability associated with building rehabilitation.			Guideline has not been modified and will be adopted as published in the draft.
63797	1	First	
●Egress guideline for residential rehabilitation.			Guideline published in this notice replaces draft guideline.
63886	2	First	
●Electrical guideline for residential rehabilitation.			Guideline published in this notice replaces draft guideline.

Guidelines as Published 44 FR 63760—Continued

Page	Column	Line	Changes
63902	2	First	
●Plumbing DWV guideline for residential rehabilitation.			Guideline published in this notice replaces draft guideline.
63908	1	First	
(Not included in draft guideline.)			Appendix added containing Plumbing DWV performance criteria.
●Guideline of fire ratings of archaic materials and assemblies.			Guideline published in this notice replaces draft guideline.
63921	2	First	
Appendix to above guideline			Appendix has not been modified and will be adopted as published in the draft.
63944	1	First	

Findings of inapplicability have been found with respect to the environment and regulatory analysis. Copies of these findings are on file in the Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410.

(Sec. 511 of the Housing and Urban Development Act of 1970)

Issued at Washingon, D.C., May 14, 1980.

Donna E. Shalala,

Assistant Secretary, Policy Development and Research, Department of Housing and Urban Development.

GUIDELINE FOR SETTING AND ADOPTING STANDARDS FOR BUILDING REHABILITATION

Table of Contents

PART I

INTRODUCTION AND BACKGROUND

Purpose of the Guidelines and Intended Users

Purpose

This guideline is intended to serve the following purposes:

(1) To present a method for describing and analyzing the existing regulatory system affecting all buildings (existing and new) in a community. This method includes identification of all pertinent codes and regulations, as well as all departments involved in their enforcement.

(2) To present a method for assessing the impact of standards set by the existing regulatory system on building rehabilitation in the community, and for identifying problems and constraints for rehabilitation.

(3) To recommend methods for amending or modifying the existing regulatory system so as to establish and enforce standards which encourage rehabilitation.

Intended Users

The following groups or individuals may use this guideline:

(1) Citizen groups (voluntary or appointed) who wish to assess the impact of the building regulatory system on rehabilitation in their community.

(2) Policymakers in city government (mayor, council, city manager, community development director, etc.) who wish to assess the impact of the existing building regulatory system on rehabilitation, and/or to amend or modify it in order to encourage rehabilitation.

(3) Code enforcement department heads (building officials) who wish to assess the need for amendment or modification of the existing building regulatory system in order to encourage rehabilitation.

Definitions

This guideline does not start off with a precise definition of "rehabilitation" and other related terms. This is intentional, because the nature of building rehabilitation which may encounter regulatory problems and constraints, and the nature of the problems themselves, are a local phenomenon. Thus, a community using this guideline may evolve its own definition of "rehabilitation", which could include any specific set of activities related to the general view of existing buildings as a resource to be conserved, rehabilitated or reused in the community's ongoing development process. What is important for the users of this guideline to realize is that there are many different kinds of rehabilitation projects and many different kinds of code-related problems, and that this and the accompanying guidelines could be useful in dealing with most of them.

INTRODUCTION TO THE REGULATION OF BUILDING REHABILITATION: STATE-OF-THE-ART

A. Building Regulations

In order to adapt or modify a jurisdiction's existing building regulatory system so as to promote rehabilitation, particularly residential rehabilitation, or in order to minimize the constraints which that system may impose on rehabilitation projects, it is first necessary to understand the building regulatory system in general terms and how that system regulates existing buildings.

A.1 How the Building Construction and Maintenance Regulatory System Regulates Existing Buildings

Communities or other jurisdictions (e.g., states) currently regulate new and existing buildings by one or more of the following five types of regulations:

- Construction codes.
- Building maintenance codes (property maintenance/housing/health/fire prevention).
- Hazard abatement codes.
- Past construction codes.
- Retroactive laws and regulations.

(1) *Construction codes.* Construction codes are generally referred to as "building codes". Actually they include a building code (regulation structural, fire, accident and health safety aspects of building), an electrical code, a plumbing code, a mechanical code and a variety of specialty codes controlling such elements as boilers, elevators, etc.

The objectives of these codes is to provide certain levels of safety, health, welfare and property protection for building occupants and for the general public. To accomplish this they regulate design, construction, repairs, use, maintenance, moving, and demolition of buildings, or portions thereof.

Building codes often provide two approaches to compliance: prescriptive and performance. The relevance of this distinction to rehabilitation will be discussed later. Codes prescribe acceptable materials, sizes and methods of construction. However, most modern building codes also provide a performance approach by providing for the acceptance of alternate materials and methods of construction. The following sections of the Uniform Building Code (UBC), Standard Building Code (SBC), Basic Building Code (BBC) and National Building Code (NBC) define this approach:

Uniform Building Code—1979 Edition

"Alternate Materials and Methods of Construction. Sec. 105. The provisions of this code are not intended to prevent the use of any material or method of construction not specifically prescribed by this code, provided any alternate has been approved and its use authorized by the building official.

"The building official may approve any such alternate, provided he finds that the proposed design is satisfactory and complies with the provisions of this code and that the material, method or work offered is, for the purpose intended, at least equivalent of that prescribed in this code in suitability, strength, effectiveness, fire resistance, durability, safety and sanitation.

"The building official shall require that sufficient evidence or proof be submitted to substantiate any claims that may be made regarding its use. The details of any action granting approval of an alternate shall be recorded and entered in the files of the code enforcement agency."

Standard Building Code—1979 Edition

"103.6 Alternate Materials and Alternate Methods of Construction. The provisions of this code are not intended to prevent the use of any material, or method of construction not specifically prescribed by this code, provided any such alternate has been approved and its use authorized by the Building Official. The Building Official shall approve any such alternate, provided he finds that the proposed design is satisfactory and complies with the provisions of Chapter XII, and that the material, method, or work offered is, for the purpose intended at least the equivalent of that prescribed in the code in quality, strength, effectiveness, fire resistance, durability, and safety. The Building Official shall require that sufficient evidence or proof be submitted to substantiate any claim that may be made regarding its use. If, in the opinion of the Building Official, the evidence and proof are not sufficient to justify approval, the applicant may refer the entire matter to the Board of Adjustments and Appeals as stipulated in Section 111."

The BOCA Basic Building Code—1978

"109.4 Alternate Materials and Equipment. The provisions of this code are not intended to prevent the use of any material or method of construction

not specifically prescribed by this code, provided any such alternate has been approved. The building official may approve any such alternate provided he finds that the proposed design is satisfactory and complies with the intent of the provisions of this code, and that the material, method or work offered is, for the purpose intended, at least the equivalent of that prescribed in this code in quality, strength, effectiveness, fire resistance, durability and safety."

National Building Code—1976

"100.7 Materials and Methods of Construction. Nothing in this Code shall be construed to prevent the use of any material or method of construction whether or not specifically provided for in this Code if, upon presentation of plans, methods of analysis, test data or other necessary information, to the building official by the interested person or persons, the building official is satisfied that the proposed material or method of construction complies with specific provisions of or conforms to the intent of this Code."

Such provisions provide local officials with a significant potential for flexibility, which can be used to encourage building conservation, rehabilitation and reuse, or to reduce constraints thereto, when existing buildings cannot easily comply with the prescriptive requirements of the codes. Traditionally, however, the "alternate materials and methods" approach has been used for approval of new products where the basis for acceptance is reasonably clear. It has been used to a much lesser degree for the acceptance of alternate design methods for meeting the intent of the code which is often the problem in building rehabilitation. There are two reasons for this: First, there is no general agreement on what is covered by the terms "materials and methods of construction." For example, some interpret these to include dimensions specified in the code (e.g., stair widths), while others consider such specifications as "design specifications" to be excluded from "materials and methods." Second, while the model codes all contain a general statement of purpose at their outset, they lack clear statements of "code intent" for the several building attributes regulated (e.g., structural safety, fire safety, accident safety, health and hygiene), and for most specific code provisions.

Building codes often give the enforcement official authority to modify code provisions in individual instances, when practical difficulties in full compliance are involved. While this modification authority provides the official with opportunity to exercise judgment, it is not adequate for use as a general vehicle for the encouragement of building conservation, rehabilitation and reuse.

Construction codes may be adopted at the state or the local level, depending on state law. The various specialty codes (building, electrical, plumbing, etc.) may be enforced by one agency or by various agencies of government. These options may have significant impact on building regulation in general, and on building conservation, rehabilitation and reuse in particular.

The enforcement of provisions of construction codes is usually triggered by an application for a permit (building, electrical, plumbing) to construct.

Construction codes are periodically updated. The model codes, which are adopted by many jurisdictions, are updated and republished every three years, with amendments published periodically between each new edition. The updating of codes involves five types of code modification:

- Elimination of references to materials and methods of construction no longer used in modern construction (i. e., "archaic" materials and methods).
- Addition of reference to new materials and methods of construction.
- Addition of new requirements.
- Modification of administrative provisions.
- Change in required levels of performance.

It is believed that, in general, the updating of codes represents a constant increase in the specified levels of safety, health, welfare, and property protection. While this statement is in need of proof, and while notable instances of reduction in codes change periodically in response to changing technology, new materials and products, and the changing needs of building occupants and the community at large. A building constructed to a past building code is not likely to meet all provisions of the current code.

Building codes regulate building rehabilitation and reuse in several ways, which are discussed in Section B. of this part.

(2) *Building Maintenance Codes (Property Maintenance/Housing/ Health/Fire Prevention).*

The basis for adopting property maintenance codes is contained in the building codes. The three model building codes, and nearly all other modern building codes, contain sections which require that all building, built under current or previous codes be maintained in a safe and sanitary condition.

It is apparent that building codes requiring maintenance and repair allow repairs to be made in a manner consistent with the original construction system. Where materials are no longer available (wood lath for example) a modern-day counterpart can be used.

Maintenance essentially means that the structural, fire, and health and safety features of a building be maintained at levels comparable to those existing at the time the building was constructed.

Communities may regulate existing buildings by means of property maintenance codes. Most widely used of these are housing (or health) codes. Housing codes have traditionally been used for establishing minimum levels of health in existing residential occupancies (one and two family dwellings, apartments and hotels). Property maintenance codes contain the requirements of the housing code plus requirements applicable to other occupancies. Housing codes contain many specific requirements, while property maintenance codes tend to be more performance based (containing general statements of objectives).

Fire preventiuon codes are also a form of property maintenance code. They are intended to control the fire hazards in buildings by proper operation and maintenance procedures.

Housing codes and fire prevention codes are adopted either by the state or local government. They are often enforced by a different agency from that charged with enforcing the building code. The enforcement of these codes is usually triggered by complaints and by routine periodic inspections (the latter often concentrating on selected occupancies or selected neighborhoods). In some communities, the enforcement of these codes may also be triggered by periodic license or permit requirements (e.g., business license, fire marshal's permit, etc.). It is likely that in many communities there is a significant number of buildings which do not comply with the housing and/or fire prevention codes, due to the limitations on resources available for routine inspection of all buildings. Often, housing code enforcement is done by persons with special sensitivity to the needs of residents—a feature which may be of potential benefit for the encouragement of building conservation, rehabilitation and reuse.

General property maintenance codes are usually adopted by local government, since they are applicable to any occupancy. However, their adoption is not widespread.

Housing codes and property maintenance codes cover many of the same attributes of buildings regulated in new construction codes. For these same attributes, however, they usually

establish levels of health, safety and welfare which are lower than the respective levels established by the new construction codes. The actual levels established by the maintenance codes are not usually stated as explicitly, as in construction codes.

The enforcement of housing and property maintenance codes often becomes the basis for mandatory repairs (see Section B below) in existing buildings. However, by providing a baseline level of health and safety for existing residential and/or other buildings, these codes may be employed to encourage building conservation, rehabilitation and reuse.

(3) *Hazard Abatement Codes.* Codes for the Abatement of Dangerous Buildings, or similarly titled documents, provide a basis for measuring or evaluating the condition of an existing building. These codes very carefully provide for due process to ensure that the enforcing body acts legally when it deems a building to be dangerous and requires its repair, evacuation, or demolition.

Both the International Conference of Building Officials (ICBO) and the Southern Building Code Congress International (SBCCI) publish a code for the Abatement of Dangerous Buildings. The Building Officials and Code Administrators International (BOCA) includes similar provisions within the Basic Building Code.

These codes include fairly easily implemented provisions for structural analysis, and give specific limits for material stresses. The requirements for fire safety, accident and health generally refer back to the code under which the building was built, and address how the required building safety elements are currently operating and are maintained. These requirements are stated in general performance language.

Hazard abatement codes have traditionally been used as the means to secure demolition of buildings. Their enforcement is usually triggered by complaints, inspections or any other actions which bring the potential hazard to the attention of the authorities.

These codes establish levels of safety and health which are lower than those established in building codes for new construction. It may be implied that these levels are also lower than those of property maintenance codes.

Implied in all building regulations, and in hazard abatement codes, is the concept of "imminent hazard". This is the absolute lowest level a building can reach. The discovery of an "imminent hazard" in a building will justify drastic enforcement without permitting any delay in correction. While not specifically defined in the codes, a guideline for determining "imminent hazard" is included in Part III of this Guideline.

(4) *Past Construction Codes.* As discussed earlier, the implication contained in most building codes and property maintenance codes is that the minimum requirement for an existing building is that the building, and any required safety equipment and devices, be maintained to the level required by the code under which the building had been constructed. As discussed earlier, these past codes establish levels of health, safety, welfare and property protection which are different from, and are usually lower than, those of current new construction codes.

(5) *Retroactive Laws/Regulations.* In some cases States or local governments have declared certain building features unsafe, or otherwise undesirable, and have required that all buildings of a certain occupancy or class be altered to remove the unsafe or undesirable condition, or to install some specific feature making the building appropriately safe or desirable.

Examples of such retroactive regulations are:

- High-Rise Requirements Adopted by the California State Fire Marshal.
- City of Los Angeles Stairway Enclosure Requirements for Hotels, Apartments and Similar Residential Buildings Exceeding Two Stories in Height.
- City of Los Angeles Preliminary Draft of "Earthquake Hazard Reduction in Existing Buildings," currently being considered for adoption. This draft deals potentially with all building occupancies, reclassifying them into four hazard classifications.
- Appendix Chapter 12 of the 1979 Uniform Building Code, "Existing Buildings". This chapter is applicable to existing nonconforming Group R, Division 1 occupancies (hotels, apartment houses, convents and monasteries) more than two stories in height. (See Appendix 1 of this guideline.)

In all cases, existing buildings covered by the retroactive regulations are required to be modified to conform to the new minimum provisions. The levels of health, safety, welfare and/or property protection required by such retroactive regulations may be the same as, or lower than, the respective levels required by codes for new construction.

The enforcement of a retroactive regulation is triggered by inspections called for by the regulation itself. Often the enforcement is constrained by the commmunity's available resources, in which case the community may establish a schedule for enforcement based on neighborhood location, type of building or other factors.

A.2 Continued Use and Occupancy—Building Codes and Existing Buildings

Building codes traditionally permit the continued use and occupancy of buildings in existence at the time of the adoption of the code. This is often referred to as the "non-conforming rights" of existing buildings. Section 104(c) of the 1979 edition of the Uniform Building Code is a case in point:

"Existing Occupancy. Buildings in existence at the time of the adoption of this code may have their existing use or occupancy continued, if such use or occupancy was legal at the time of the adoption of this code, provided such continued use is not dangerous to life."

Section 105.1 of the 1978 edition of the Basic Building Code reads as follows:

"Continuation of existing use: The legal use and occupancy of any structure existing on ——— (date of adoption of this code) or for which it has been heretofore approved, may be continued without change, except as may be specifically covered in this code and the housing code or as may be deemed necessary by the building official for the general safety and welfare of the occupants and the public."

Similar code sections occur in other modern building codes used throughout the United States. Accordingly, in order to mandate that an existing building be repaired or brought up to some minimum condition of safety, one of three possibilities exists:

- establish that a building is dangerous in accordance with a hazard abatement code or similar regulation;
- enforce a property maintenance code; or
- enforce a retroactive law or provision.

A.3 Levels of Health, Safety, Welfare and Property Protection

The preceding discussion has alluded to the various levels of health, safety, welfare and property protection implied by the varioius codes and regulations being discussed—with new construction codes defining the highest, and hazard abatement codes defining the lowest. It may be useful for communities considering setting or adopting standards for building rehabilitation to formalize this concept of levels of performance required by the various codes and regulations.

For each major objective of codes—health, safety, welfare, and property protection—one can conceive of a scale of performance. New construction code

requirements may be thought of as generally defining the upper limits of such a scale; hazard abatement codes may be thought of as defining the lower limits of such a scale (with "imminent hazards" being specific points below or at the lower limit). Property maintenance codes and past building codes may be viewed as occupying given points between those limits. This concept is shown in diagram 1.

An existing (legal) building may be thought of as embodying levels of health, safety, welfare and property protection anywhere between these limits or above the upper limit. Retroactive laws and regulations may mandate the upgrading of such a building to some specified level (with regard to a specific code objective or attribute). However, when such a building is rehabilitated, the existing set of regulations, as discussed earlier, will explicitly or implicitly require that building to reach a specified new level. The following section of this Part (Section B) discusses how this new level of performance is currently specified by building regulations.

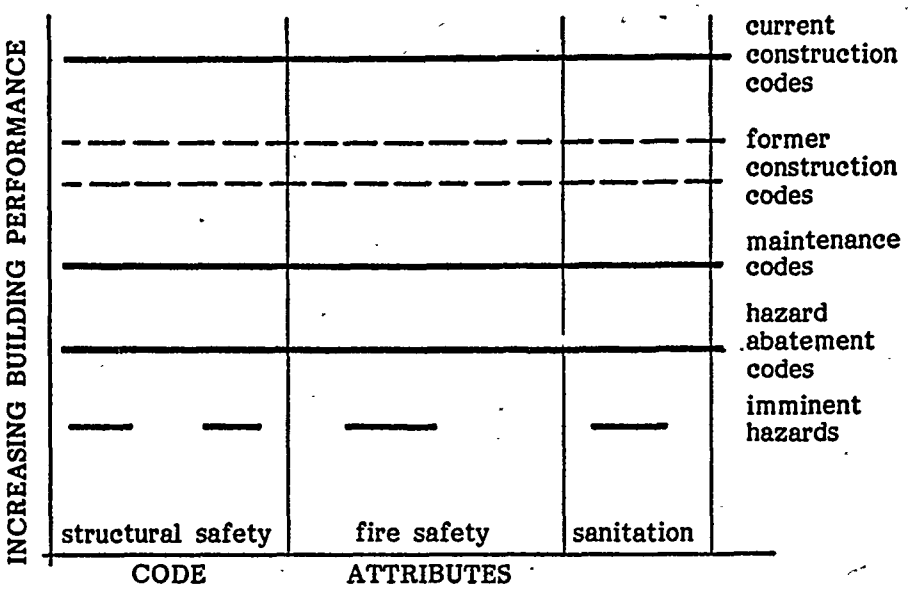

Diagram 1.
Conceptual Diagram of Various Levels of Building Performance Implied by Various Types of Building Regulations

While this concept of "levels" may be useful in considering building rehabilitation, it should be kept in mind that it may not be possible to actually quantify or measure a given level, or the difference between levels (e.g., egress potential of current codes and older codes).

Finally, for every level which is specified by a set of code requirements, the "alternative materials and methods" provision of modern building codes (as discussed earlier) recognizes that a given level can be achieved by alternatives to compliance with the code requirements. Such alternatives achieve equivalent performance. It is essential to make a clear distinction between equivalent performance (achieved by alternative means) and reduced performance.

B. Implication of Current Regulations for Building Rehabilitation

B.1 Current Regulations and Building Rehabilitation

In general, building codes address building rehabilitation in two categories:

- Maintenance, alteration and repair of existing buildings not involving a change of use or a change of occupancy.
- Change of use or occupancy in existing buildings.

(1) *No Change of Use or Occupancy (25–50%).* Rehabilitation work involving no change of use or occupancy can be further qualified into two distinct categories:

- Voluntary maintenance, alterations or repairs (modernization, upgrading, etc.).
- Mandatory maintenance, alterations or repairs.

Voluntary repairs or maintenance of a building and its facilities involves work which is to conform to the code under which the building was initially constructed. The idea and action are voluntary. Rehabilitation work in this category is in general included in the building's non-conforming rights under the building code, although it may trigger the correction of a host of violations considered hazardous which are unrelated to the voluntary work. It may also trigger degrees of compliance with new construction codes through the 25–50% Rule to be discussed below. Whatever requirements are imposed, their enforcement is triggered, in this case, by an application for a construction permit (building, electrical, plumbing, etc.).

Mandatory repair or maintenance results in a building and its facilities being required to comform to a level of safety as defined by law (codes for the abatement of dangerous buildings, property maintenance codes, housing codes, and/or specific retroactive provisions). The applicant may be given a period of time to comply. The idea and action are mandatory. Rehabilitation work in this category may trigger degrees of compliance with new construction codes through the 25–50% Rule.

Commonly, building codes control rehabilitation with no change of use by means of the 25–50% Rule.

According to research done by the National Conference of States on Building Codes and Standards (NCSBCS), the 25–50% Rule first appeared in building codes as part of provisions dealing with fire districts and was applied to buildings which were non-conforming within the fire district. As population and usage density increased in urban areas and several fire disasters occurred, communities became increasingly aware of the danger of fire literally consuming whole areas of a city where many buildings were of wood frame construction. The criterion of 50% of value was used to require demolition, or replacement of frame exterior walls with conforming construction. In other words, according to this research, the original purpose of the rule was to *prevent* rehabilitation of certain classes of buildings.

The actual wording of the 25–50% Rule in the four model codes is contained in the following sections:

- Basic Building Code, Section 106.0
- Standard Building Code, Section 101.4
- Uniform Building Code, Section 104
- National Building Code, Section 104.3

In the 1979 edition of UBC, Section 104 has been revised to drop all references to cost of rehabilitation. For the purposes of the following discussion, reference to the UBC version will be to the 1976 edition, since many jurisdictions are still using this edition. There are certain similarities and differences among the four versions which should be noted.

a. Over 50%. The BOCA Basic Building Code (BBC), the SBCCI Standard Building Code (SBC), and the 1976 edition of the ICBO Uniform Building Code (UBC) all contain the basic 25–50% Rule. The American Insurance Association (AInsA) National Building Code (NBC) contains reference only to restoration if cost exceeds 50%. All four of the codes are consistent in requiring that the entire building be brought into compliance with current code requirements if the cost of the work exceeds 50% of the value of the building. The NBC apparently does not administratively address the issue if restoration costs are below 50% of value. Hence, the balance of this discussion is primarily directed to the three remaining model codes.

Both the BBC asnd SBC state that the physical value of the building will be determined by the building offical. The BBC also states the value will be based on replacement cost.

All three models indicate that the rule applies only if the alteration or repairs are made within a 12-month period.

BBC and SBC differentiate between alterations exceeding 50% and repair of damages exceeding 50%. The 12-month period does not apply to the repair of a building damaged in excess of 50% in value.

b. Between 25–50%. Where the cost of the alteration is between 25 and 50% of value of the building, both BBC and SBC specify that the extent to which the portion of the building altered or repaired be made to conform to new construction requirements is left to the discretion of the building official. The UBC (1976 edition) states that the addition, alteration or repair be made in conformance with the current code, provided that the entire building not exceed areas and heights specified by the code.

c. Under 25%. Where the cost of the alteration if under 25%, BBC and SBC essentially allow restoration with like materials with caveats that the public safety is not endangered or a non-conforming or hazardous use is not extended.

In the under 25% category, the UBC (1976 edition) distinguishes between structural and non-structural alterations. For structural alterations, the changes must conform to new code requirements, unless they are minor, in which case the building official may approve replacement with like materials, provided that the entire building not exceed areas and heights specified by the code. Non-structural alterations and repairs can be made with like materials provided they do not affect any member or part of the structure having required fire resistance.

Jurisdictions that use the 25–50% Rule at times vary the terms from those in the model codes. Two examples are Los Angeles and Phoenix.

Los Angeles may be said to have a 10-50% rule, related to location with respect to fire districts. The Building Code of the City of Los Angeles, 1976 edition states:

"Sec. 91.0103—Application to Existing Building

* * * * *

(d) Alterations. Any alterations may be made to any building in any location provided the building as altered conforms to the requirements of the Los Angeles Municipal Code for new buildings in the same location.

Exceptions: 1. Alterations or repairs to any existing non-conforming building outside of every Fire District may be of the same type of construction as the existing building, provided the aggregate value of such alterations or repairs in any two-year period does not exceed 50 per cent of the replacement value of the building.

2. Alterations or repairs may be made to any building in any location provided the new construction conforms to that required for a new building of like area, height and occupancy in the same location."

"Sec. 91.1603—General Requirements

* * * * *

(b) Nonconforming Buildings. Alterations and repairs to a nonconforming building in a Fire District may be of the same type of construction as the existing building if the aggregate value of such repairs, in any one year, does not exceed 10% of the replacement cost of the building.

Alterations or repairs in excess of 10% of the replacement cost of the building or structure may be made provided all of the repairs and the new construction conform to the materials and type of construction required for a new building of like area, height and occupancy in the same location.

Whenever a nonconforming building or structure has been damaged, or is in need of repairs or alterations required by the Los Angeles Municipal Code in an amount exceeding 50% of the replacement cost, the entire building or structure shall be made to conform to the Code or shall be demolished."

The City of Phoenix, Arizona, briefly reported the following information:

If Cost of Repair is:
0–10%—Replace with like material
10–50%—New work must meet code
Over 50%—Entire building must meet code

In summary, the 25–50% Rule requires the upgrading of existing buldings to the performance levels required for new construction if work exceeds 50%, and allows various lower levels to continue to exist in buildings when lesser work is involved. It should be noted that the "alternate materials and methods" provisions of building codes, while generally applicable to *all* provisions of the codes, is not explicitly referenced in relation to compliance with the 25–50% Rule.

The 25–50% Rule has been the target of much criticism with regard to its effects on building conservation, rehabilitation and reuse. This criticism is underlined by the fact that originally the Rule was not intended to deal with rehabilitation. The drawback of the 25–50% Rule is that it is arbitrary, and it may unintentionally or by default force a rehabilitated building into complete new construction code compliance, when the 50% is exceeded. Furthermore, the 25–50% Rule has an adverse effect on the rehabilitation of buildings of a low value, and may discriminate between similar buildings located in different real estate markets.

In terms of the conceptual diagram of performance levels discussed in A.3 above, the 25–50% Rule requires rehabilitated buildings to be upgraded to three potentially different levels of performance.

While the 25–50% Rule may be eliminated from all the model codes in the foreseeable future, it is currently found in many local codes. It should be noted that when used in close conjunction with the "alternate materials and methods" provision, and when applied to the lower range of values, the Rule is often seen as a flexible tool for the encouragement of rehabilitation, by explicitly extending the building's non-conforming rights. As such, it will be discussed later in this guideline.

As stated previously, ICBO has eliminated the 25–50% Rule from the 1979 edition of the UBC and substituted the following wording:

"Application to Existing Buildings and Structures. Sec. 104. (a) General.—Buildings and structures to which additions, alterations or repairs are made shall comply with the requirements of this code for new facilities except as specifically provided in this section. See Section 1210 for provisions requiring installation of smoke detectors in existing Group R, Division 3 Occupancies.

(b) Additions, Alterations or Repairs.—Additions, alterations or repairs may be made to any building or structure without requiring the existing building or structure to comply with all the requirements of this code provided the addition, alteration or repair conforms to that required for a new building or structure. Additions, alterations or repairs shall not cause an existing building or structure to become unsafe or overloaded. Any building so altered, which involves a change in use or occupancy, shall not exceed the height, number of stories or area permitted for new buildings. Any building plus new additions shall not exceed the height, number of stories and area specified for new buildings.

Alterations or repairs to an existing building or structure which are nonstructural and do not adversely affect any structural member or any part of the building or structure having required fire resistance may be made with the same materials of which the building or structure is constructed.

Exception: The installation or replacement of glass shall be as required for new installations."

In essence, the 1979 UBC Section 104(b) now requires that for additions, alterations, or repairs:

- new work must conform to the code,
- work shall not cause existing buildings to become unsafe or overloaded,
- altered buildings involving change in use or occupancy, and buildings undergoing addition, shall not exceed height and area required for new buildings, and
- non-structural work not adversely affecting a structural member or any part having required fire resistance may be done with same materials.

As compared to the former Sections 104(b) through 104(e) (25–50% Rule) the new section appears to accomplish the following:

- Any amount of non-structural work can now be done with like materials, as compared to work amounting to 25% or less under the prior rule;
- Any new structural work must be in conformance with current code (which constitutes no change from the prior rule in the 0–50% bracket),

- With the caveats noted regarding overloading and height and area restrictions, the existing structure can remain without being brought up to new code requirements.

This UBC substitution for the 25–50% Rule requires the upgrading of rehabilitated buildings to a performance level somewhat lower than that required for new construction, while requiring new construction performance for specifically defined aspects.

A similar substitution to the 25–50% Rule was recommended by the BOCA Code Change Committee in January, 1980, and will be voted on by the BOCA membership in June, 1980.

(2) Change of Use or Occupancy. Building codes address change of use or occupancy in existing buildings by considering that such a change may introduce new or greater hazards and by requiring a careful reexamination to determine that the building will be safe for the new occupancy.

The three model building codes require, generally, that where a change in occupancy occurs, the building must be made to comply with the requirements of the current building code for the new occupancy. The model codes state this in various ways.

The 1978 BOCA Basic Building Code addresses change of use in three sections:

"105.2 Change in use: It shall be unlawful to make any change in the use or occupancy of any structure which would subject it to any special provision of this code without approval of the building official, and his certification that such structure meets the intent of the provisions of low governing building construction with a proposed new use and occupancy, and that such change does not result in any greater hazard to public safety or welfare."

"119.2 Buildings hereafter altered: A building or structure hereafter enlarged, extended or altered to change from one use group to another or to a different use within the same use group, in whole or in part, and a building or structure hereafter altered for which a certificate of use and occupancy has not been heretofore issued, shall not be occupied or used until the certificate shall have been issued by the building official, certifying that the work has been completed in accordance with the provisions of the approved permit; except that any use or occupancy, which was not discontinued during the work of alteration, shall be discontinued within thirty days after the completion of the alteration unless the required certificate is secured from the building official."

"119.4 Changes in use and occupancy: After a change of use has been made in a building or structure, the reestablishment of a prior use that would not have been legal in a new building of the same type of construction is prohibited unless the building complies with all applicable provisions of this code. A change from one prohibited use, for which a permit has been granted, to another prohibited use shall be deemed a violation of this code."

Section 101.4(e) of the 1979 Standard Building Code states:

"If the occupancy of an existing building is entirely changed the building shall be made to conform to the requirments of this code for the new occupancy. If the occupancy of only a portion of an existing building is changed and that portion is separated from the remainder as stipulated in Section 403, then only such portion need be made to conform."

Section 502 of the 1979 Uniform Building Code states in part:

"No change shall be made in the character of occupancies or use of any building which would place the building in a different division of the same group of occupancy or in a different group of occupancies, unless such building is made to comply with the requirements of this code for such division or group of occupancy.

Exception: The character of the occupancy of existing buildings may be changed subject to the approval of the building official, and the building may be occupied for purposes in other groups without conforming to all the requirements of this code for those groups, provided the new or proposed use is less hazardous, based upon life and fire risk than the existing use."

The SBC unambiguously requires compliance with current code provisions. The UBC is similar, but includes the *Exception* which waives compliance with *all* current code provisions (i.e., requires compliance with *some* only). The *Exception* is in performance language, and the enforcment official must determine whether the proposed use is less hazardous based on life and fire risk than the existing use. The UBC does not define "life and fire risk". A decision must be made whether it was intended to apply to property damage as well as to life safety of the occupants.

The BBC appears to give the enforcement official the greatest leeway (of the three model codes) in determining the extent to which compliance with current code provisions would be required.

In summary, the model codes vary in their requirements for rehabilitation involving a change in use or occupancy. At one extreme they require upgrading to the performance levels of new construction. At the other, they require selective upgrading, based on undefined hazard and risk analyses. Here also, as in the case of the 25–50% Rule, explicit reference to the "alternate materials and methods" provision in cases of change or use or occupancy is not made.

B.2 "Code Enforcement Guidelines for Residential Rehabilitation", Published by BOCA

The document, entitled "Code Enforcement Guidelines for Residential Rehabilitation", the first edition of which was published in 1975, was developed by BOCA, ICBO, SBCCI and AInsA on the basis of research sponsored by the U.S. Department of Housing and Urban Development.

The document is currently published as Appendix B to the 1978 BOCA Basic Property Maintenance Code.

The extent and nature of the application of this document to residential rehabilitation in local communities is not known at this time.

B.3 Possibility of Conflicting Goals of Regulations and Rehabilitation

Building regulations, as discussed earlier, are intended to implement goals of private and public health, safety, welfare and property protection in the occupancy and use of buildings. These goals are usually not explicitly stated by a community. Their achievement through the enforcement of building regulations imposes certain costs on building owners and on society.

Programs of building conservation, rehabilitation and reuse are also initiated by communities in the furtherance of certain goals. These goals may relate to avoiding the reduction of the existing housing stock, or to preventing the deterioration of downtowns or of industrial areas.

It is useful for a community to realize, whether explicitly or implicitly, that the goals of its rehabilitation and community development program may conflict with the goals underlying its current building regulation program. In such a case, the enforcement of building regulation will not support the community's rehabilitation goals. Specifically, current building regulation may force the upgrading of rehabilitated buildings to the levels required for new construction (as discussed above), which may impose an unacceptable cost on rehabilitation and may prevent rehabilitation from taking place.

If a community finds that its regulation and rehabilitation goals are potentially in conflict, it may determine that in the interest of furthering

rehabilitation, some reduction in the levels of performance (safety, health, welfare and/or property protection) required of rehabilitated buildings may be acceptable. A community which develops a rehabilitation policy on the basis of such a determination will find the concept of the various levels of performance introduced in A.3 above useful in implementing such a policy. The concept may help the community to set specific standards and requirements for rehabilitation that are different from the regulation currently in effect.

Such standards and requirements may imply lower levels of performance than required for new construction, while reflecting acceptable levels of safety for the community.

The following diagram illustrates the levels of performance of a specific existing building, in relation to the performance level required by various regulations in effect. It suggests the potential benefits of establishing specific requirements for building rehabilitation, because in their absence the current 25–50% Rule and change of occupancy provisions often force the building up to the performance levels of the new construction codes.

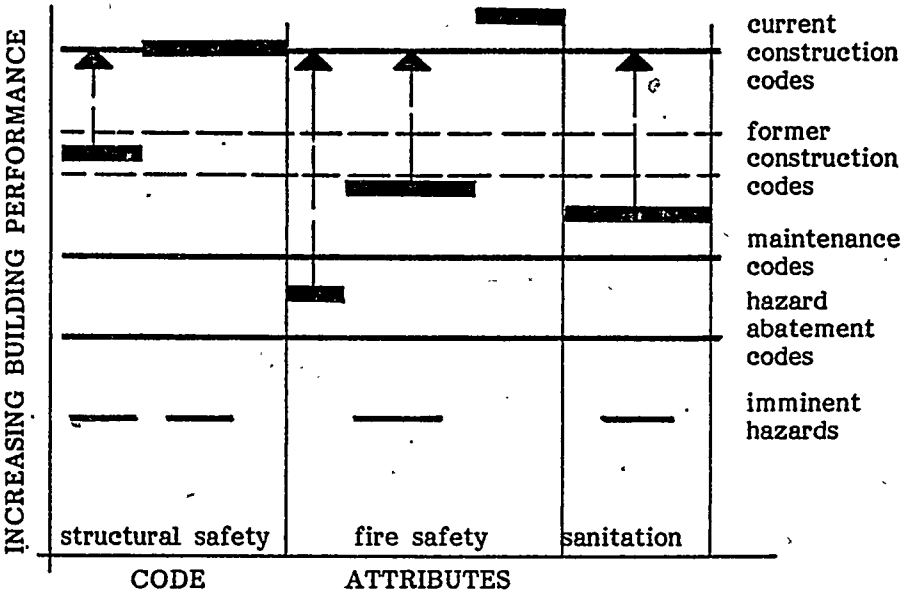

Diagram 2.
Conceptual Diagram of the Extent of Rehabilitation Work (Indicated by Arrows) Imposed on an Existing Building by Current 25–50% Rule and Change of Occupancy Provisions. (Each bar represents a special building component such as DWV system, stairs, structure, etc.)

C. Historic Preservation

A discussion of the state-of-the-art of regulation of building rehabilitation would not be complete without mentioning historic preservation. Historic preservation is a specific problem, and in addressing it the building regulatory system has accepted the fact that in achieving the policy goals of historic preservation, some compromise with the health and safety goals of the regulatory system may be required. This compromise has been recognized by the model code groups.

The 1978 BOCA Basic Building Code States:

"Section 316.0 Special Historic Buildings and Districts. 316.1 Approval: The provisions of this code relating to the construction, repair, alteration, enlargement, restoration and moving of buildings or structures shall not be mandatory for existing buildings or structures identified and classified by the state and/or local government authority as historic buildings, subject to the approval of the board of appeals when such buildings are judged by the building official to be safe and in the public's interest of health, safety and welfare regarding any proposed construction, alteration, repair, enlargement, relocation, and location within the fire limits. All such approvals must be based on the applicant's complete submission of professional architectural and engineering plans and specifications bearing the professional seal of the designer."

Section 104.(f) of the 1979 Uniform Building Code states, similarly:

"(f) Historic Buildings. Repairs, alterations and additions necessary for the preservation, restoration, rehabilitation or continued use of a building or structure may be made without conformance to all of the requirements of this code when authorized by the building official provided:

1. The building or structure has been designated by official action of the legally constituted authority of this jurisdiction as having special historical or architectural significance.

2. Any unsafe conditions as described in this code are corrected.

3. The restored building or structure will be no more hazardous based on life safety, fire safety and sanitation than the existing building."

Briefly, buildings may be exempted from full code compliance either individually, as a landmark, or collectively in an historic district. The designation as a landmark or as an historic district may be made by local public landmarks/historic district commissions, and may rely to varying degrees on state historic preservation offices or on listing in the National Register of Historic Places, maintained by the Heritage Conservation and Recreation Service of the U.S. Department of the Interior.

D. Some Current Regulatory Innovations Related to Building Rehabilitation

Several specific examples of direct approaches to the regulation of building rehabilitation, rather than the building codes' indirect approach through the 25–50% Rule and the change of occupancy regulations are discussed briefly below. Fuller discussions and documentation of each example are included in the Appendices.

All the examples establish a set of requirements applicable to rehabilitation, and each, to varying degrees, reflects a reduction from the total set of requirements applicable to new construction. In other words, each example is a regulatory innovation which addresses the problem of setting standards for rehabilitation, and may be thought of as requiring a level of performance below the upper level implied by codes for new construction (see A.3 above).

Each regulatory innovation is likely to have grown or evolved out of a very specific set of physical and social conditions, and to have been intended to solve specific local problems.

The following examples of regulatory innovation are suggested for consideration; they are not intended to form an exclusive or comprehensive list, and similar regulatory innovations may exist elsewhere:

- Washington, D.C. (Appendix 2)
- San Francisco, California (Appendix 3)
- Denver, Colorado (Appendix 4)
- State of Massachusetts (Appendix 5)
- State of California (Appendix 6)
- City of Los Angeles Rule of General Application on Structural Changes Required by Change of Occupancy (Appendix 7)
- State of California Seismic Safety Commission Draft Legislation Related to Seismic Hazards (Appendix 8)
- Chapter 10 of the Official Electrical Code of the City of Detroit (Appendix 9)

The examples fall into two categories:

- Comprehensive approaches
- Partial approaches

D.1 Comprehensive Approaches

Examples of comprehensive approaches can be found in Washington, D.C.; San Francisco, California; Denver, Colorado; the State of Massachusetts. These approaches are comprehensive because each one of them has developed an innovative regulatory system which addresses all aspects of rehabilitation of buildings in most, or all, occupancies, with the exception of Massachusetts, which does not address electrical, mechanical and plumbing requirements.

(1) *Washington, D.C.* Washington's code includes neither the 25–50% Rule nor the general change in use regulations. In their place, the code contains prescriptive provisions specifically addressing existing buildings, and specific provisions applied when a change in use occurs. In

general, the code requires several levels of performance in increasing order:

(a) Code in effect when building was erected
(b) Retroactive provisions
(c) Provisions concerning alteration or conversion
(d) Provisions for new construction.

The code incorporates a hazard ranking by occupancy type and intensity of use. Conversion is defined as a change to a higher hazard use. Alteration is defined as work which affects egress arrangements or fire resistivity.

The code provisions were developed over a long period of time, and are based on the approach of allowing certain deviations from the requirements for new construction for existing, altered or converted buildings. The text of these provisions is provided in Appendix 2.

Prescriptive requirements for rehabilitation may be effective in an urban jurisdiction such as Washington, D.C. where the building official may be familiar with a large number of older buildings, which pose similar problems for rehabilitation. Additional prescriptive requirements may be needed to cover the range of rehabilitation problems encountered in jurisdictions with a more varied or diverse building stock.

(2) *San Francisco, California.* San Francisco's code, like Washington's, includes neither the 25–50% Rule, nor the general model code change in use provision.

San Francisco handles rehabilitation and change in use be establishing three separate approaches. These are:

- For existing residential building rehabilitation: using the San Francisco Housing Code (SFHC) together with a "Field Inspection Manual" (FIM).
- For any change in use or occupancy: using the San Francisco Building Code (SFBC) which includes a series of criteria which may lessen the specific application of new construction standards.
- For general alterations, additions and extensions, regardless of use or occupancy: setting specific criteria for the amount and type of work that may be done before requiring full compliance with present code provisions.

These separate approaches are discussed at greater length with all code references in Appendix 3.

(a) The underlying principle for the rehabilitation of existing residential buildings is that existing buildings, legally constructed at some time in the past, shall be considered acceptable today unless they do not conform to a specific list of retroactive requirements. (Sections 105 and 309 SFHC and Introduction to FIM.)

These requirments include items related to health and safety such as unenclosed stairways, exits, fire alarms, etc. The provisions in the SFHC are less strict than those required for new construction in the SFBC. For example, acceptance of smoke barriers (non-rated construction) for stairway enclosures which by SFBC would have to be 1 or 2 hour fire resistive construction (Section 807 SFHC).

The Field Inspection Manual (FIM) provides guidance to field personnel in enforcing the SFHC. In the FIM, are interpretations of conditions or configurations that have been commonly found over the years in San Francisco buildings. These interpretations provide assistance to the inspector by directly providing him the expertise of the Superintendent of Building Inspection, during the inspection. The interpretations have the force of law, based upon City Attorney opinions. The FIM has been under continuous reexamination and revision since adoption as a working tool in 1961.

(b) The change of use or occupancy provisions include that from non-residential to residential usage. The applicable requirements are contained in the SFBC. The code intent is to require a level of compliance with SFBC provisions based upon the degree to which the overall hazard to the public is increased due to the proposed change. This relative increase in hazard level is specifically provided for in the form of a matrix of original and proposed occupancies (Table No. 5.1, SFBC). With this matrix the code user can readily determine the probable degree of application of new construction standards to the particular building.

(c) Alterations, additions and extensions are handled in the SFBC based upon the principle that all new work meet present day construction standards and arrangements. Under certain circumstances areas outside of the proposed work areas may be subject to new code requirements as well. In Sections 104.B thru F, SFBC, these specfic instances are cited.

(d) There is a seismic requirement in the SFBC that only applies under certain circumstances. This requires that when the structure is to be upgraded seismically, it need only meet the lateral force levels of the SFBC (Section 104.F, SFBC). This was specifically written to permit retention of unreinforced masonry type buildings (not permitted for new buildings) provided that the seismic force levels can be resisted by structural elements such as rigid steel frames, x-bracing or shear walls. This provides a mechanism for retaining and reusing older buildings while protecting public safety.

While the San Francisco approach appears complex and does involve development of specific code philosophies and auxiliary documents, it has addressed the several problems of existing buildings, their up-grading, change of use and retention without requiring the sacrifice of public safety. It has recognized that existing buildings are a considerable asset. Most importantly, the San Francisco approach clearly separates the rehabilitation of an existing residential building from the requirements that may apply for a change in use or occupancy or those invoked by alteration, addition or extension.

(3) *Denver, Colorado.* Unlike Washington and San Francisco, the Denver building code includes both the 25–50% Rule and the general change of occupancy regulation. However, in apparent recognition of the inadequacy of these regulations to support Denver's rehabilitation needs, the City of Denver has added a special chapter, entitled "Rehabilitation of Older Buildings" to its building code (Chapter 31). This chapter achieves several results:

(a) It exempts buildings of specific occupancies erected before 1950 from code compliance under the 25–50% Rule and the change of occupancy regulation.

(b) It declares that, as a matter of policy, rehabilitation of older buildings is a public necessity.

(c) It establishes an administrative mechanism for developing guidelines to be used by the building official in accepting deviations from code requirements in cases where the rehabilitator requests such deviations.

Thus, Denver's regulatory innovation is to explicitly permit deviations from strict code compliance in the case of rehabilitation. It is unclear whether Denver's guidelines imply reduced levels of performance for rehabilitation when compared to new construction requirements, or whether they merely encourage the acceptance of alternative solutions of equivalent performance. Denver's approach is too recent to provide a response to this question.

The City of Denver reports that Chapter 31 is being utilized for the rehabilitation of Denver landmarks, designated historic places, and recently, for other buildings built before 1950. In all cases, it is reported that approvals consider public safety as paramount.

Chapter 31 is published in Appendix 4.

(4) *State of Massachusetts.* Until June, 1979, the State building code in

Massachusetts included the 25–50% Rule and the general change of occupancy regulation (the BOCA code version). On that date the State enacted Article 22, representing a regulatory innovation replacing the 25–50% Rule and the change of occupancy regulation.

In general, Article 22, contains the following:

(a) Definition of hazardous conditions, related to structural performance, number of exits and capacity of exits. These must be eliminated in all existing buildings.

(b) Classification of all occupancies into one of eight hazard classifications, in increasing order of hazard.

(c) Establishment of three levels of required performance for rehabilitated buildings (above the level of hazard elimination noted in (a) above). These levels are a function of the relative change in hazard classification involved in the rehabilitation, and range from a requirement of not reducing the level of performance of the existing building to full compliance with the requirements for new construction.

(d) Explicit encouragement of acceptance of equivalent alternative solutions whenever compliance with new construction requirements is specified.

In summary, the Massachusetts approach is based on the philosophy that the existing building's actual level of performance establishes the level to be complied with in rehabilitation, except for the elimination of a few specified hazards, and except when changing occupancy to one of substantially greater hazard. In other words, the Massachusetts approach to rehabilitation requires compliance with many different potential levels of performance (potentially the number of levels is the number of existing buildings).

There is not yet enough experience to judge the efficacy of this approach, and speicifically the efficacy of basing levels of compliance on a single number hazard index of occupancies.

Massachusetts Article 22 is published in Appendix 5.

D.2 Partial Approaches

Partial approaches to regulatory innovation related to rehabilitation of existing buildings are those which address a specific problem, be it a single hazard (e.g., sesimic loading), a single building component (e.g., electrical system), a single class of buildings (e.g., residential), or any other problem for rehabilitation.

Four examples of partial approaches to regulatory innovation are discussed below and in the appendices.

(1) *State of California.* The State of California has a statewide mandatory code applicable to residential occupancies. The State Housing Law requires that local jurisdictions adopt regulations which are "substantially the same" as those contained in the Uniform Building Code. Some variance is allowed, based on local conditions.

In 1974, the State Housing Law did away with the 25–50% Rule (which at that time was still included in the Uniform Building Code). It did not address the change of occupancy regulation (which would apply to changing use within the residential occupancies, such as apartment house to hotel, or single family dwelling to apartment house, and to change of other occupancies, not governed by the State Housing Law, into housing). The 1974 Law did so by means of several inter-related regulations (see Appendix 6):

- Explicity defining "substandard building" as defined in the Uniform Housing Code (Chapter 10), but excluding (within limits) room and space dimensions from that definition (Chapter 10, Sec. 1001 (b) 9., Uniform Housing code, 1979 Edition), and somewhat liberalizing the definition of hazardous wiring, plumbing and mechanical equipment (ibid, Sec. 1001 (e), (f), (g)). The latter is achieved by stating that if wiring, plumbing and mechancial equipment has been maintained in good and safe condition and is working properly, "it shall be deemed to have conformed to applicable law in effect at time of installation".
- Adoption of specific regulations related to structural fire safety and fire resistant exists (California Administrative Code, Title 25, Chapter 1, Subchapter 1), which are based on an earlier version of Uniform Building Code, Appendix Chapter 12, Existing Buildings, with provision for several exceptions which may be more lenient.
- Specifically stating that state or local regulations governing alteration and repair of existing buildings and moving of apartment houses and dwellings shall permit replacement, retention and extension of original materials and methods, so long as the building does not become a substandard building as defined by the Law.

The State Housing Law also establishes several other detailed requirements related to specific building elements.

The State of California has also enacted a "State Historical Building Code" (Section 18950), the intent of which is ". . . to provide a means to preserve the historical value of designated buildings and concurrently to provide reasonable safety from fire, seismic forces or other hazards to occupants." (Note omission of the usual phrase "and general public".)

The Department of Housing and Community Development of the State of California is currently preparing two documents entitled "Residential Rehabilitation Guidelines" and "A User's Residential Rehabilitation Guide", which amplify and explain the relevant parts of the State Housing Law and related laws and regulations, and provide guidance in defining electrical, mechanical and plumbing hazards.

(2) *City of Los Angeles Rule of General Application on Structural Changes Required by Change of Occupancy.* This regulatory innovation deals only with seismic loads, and illustrates the conscious reduction in requirements applicable to rehabilitation involving a change in occupancy.

The City of Los Angeles has developed a "Rule of General Application" (RGA) to determine when buildings undergoing a change of occupancy or having an increase in the occupant load must be made to conform to current structural requirements. A copy of the rule is included in Appendix 7. A portion of the rule reads as follows:

"In buildings constructed on or after October 6, 1933, a change in occupancy may be made to establish any occupancy classification provided the building is not substantially altered."

The October 6, 1933 date was selected since all buildings constructed in the City of Los Angeles subsequent to October 6, 1933 were required to be designed for earthquake forces. This provision is based upon buildings located in areas subject to seismic forces of the magnitude anticipated in Seismic Zone 4. It is recognized that the level of seismic design force would not be as required under the current building code. However, the building should perform in such a manner as to minimize life loss in the event of an earthquake.

This RGA contains a list of occupancies arranged in order from the least hazardous to the most hazardous. An occupancy or use is generally considered more hazardous as the occupant load within the building or the length of time the building is occupied are increased.

Note that an occupancy hazard listing based on structural performance may not be applicable for consideration of fire safety of the occupants.

(3) *State of California Seismic Safety Commission Draft Legislation Related to Seismic Hazards.* In areas subject to earthquakes, it is well known that unreinforced masonry buildings which have not been designed for seismic effects may be subject to severe damage in moderate earthquakes. Based upon this fact, the Seismic Safety Commission of the State of California is developing legislation related to buildings which would be a hazard when subjected to the level of seismic forces which could be encountered in the State of California. A draft of the proposed legislation is contained in Appendix 8.

This example of regulatory innovation is a form of a hazard abatement code, and is intended to eliminate the problem of complying with portions of the new construction code in removing a particular hazard.

In part, the draft states this directly:

"This bill would authorize a city, city and county, or county to establish construction standards for reconstruction of existing buildings determined, as specified, to be a hazard to life in the event of an earthquake, which standards are as specified in the bill and would eliminate the problem of complying with the latest building code governing new construction when rehabilitating older buildings."

(4) *Chapter 10 of the Official Electrical Code of the City of Detroit, Adopted November 9, 1977 ("Minimum Standards for Existing Dwelling Units").* This Chapter (see Appendix 9) was developed by the City of Detroit and has been proposed for the National Electrical Code. It reflects that city's need to rehabilitate large numbers of single family houses.

Chapter 10 covers the re-wiring of existing inadequately wired dwelling type occupancies. It describes the evidence of inadequacy of wiring, and defines minimum illumination and power requirements for each room or space of the dwelling.

Chapter 10 represents a regulatory innovation because the National Electrical Code does not specifically address existing buildings, and its requirements establish levels of performance for new construction. Chapter 10 establishes lower levels of performance which would be safe and acceptable for existing buildings.

PART II—IDENTIFYING EXISTING CONDITIONS IN A COMMUNITY

The purpose of this Part of the Guideline is to provide policymakers or other interested groups in a community with a procedure for examining the existing conditions in their community to determine what problems, if any, are posed by the existing regulatory system in setting standards for building rehabilitation and re-use. The procedure makes reference to the general introduction and background discussions in PART I of the Guideline, and consists of three steps:

- Define existing regulatory system.
- Define pertinent characteristics of building rehabilitation in the community.
- Identify potential problems.

With identification of problems, policymakers can proceed to PART III of the Guideline, in which recommendations for amending the regulatory system designed to solve the respective problems are discussed.

A. Define Existing Regulatory System

Buildings in a community may be regulated by means of a variety of regulations, as discussed in *Introduction and Background.* That discussion concentrated on the model codes, but a particular community may use model codes, modified model codes or codes of its own.

It is necessary to define how buildings are regulated in a particular community. In doing so, it will be useful to make use of the conceptual diagrams of required building performance presented in the *Introduction and Background.*

The definition of the existing regulatory system consists of four parts:

- Define those requirements imposed on all existing buildings, and their enforcement.
- Define new construction requirements and their enforcement.
- Define existing provisions addressing building rehabilitation and reuse.
- Compare criteria levels.

A.1 Define Those Requirements Imposed on All Existing Buildings, and Their Enforcement

(1) Hazard Abatement Code

(a) Determine whether a code for the abatement of dangerous buildings, or a similarly titled document, is in effect as a hazard abatement code in the community. Note that similar provisions may be part of the building code.

(b) If such a code or provisions are in effect, determine whether they include explicit criteria for various enforcement options by the authority having jurisdiction. Such criteria may be found in inspection manuals or similar ancillary documents as well as in the regulations themselves. Specifically, determine whether the code contains a workable definition of "imminent hazard", warranting immediate remedial action to be enforced by the authorities. If the criteria are defined by reference to another code (e.g., building code, electrical code, etc.), the explicit criteria should still be identified.

(c) Exhibit the criteria for "imminent hazard" and for other hazards covered by the hazard abatement code, in the categories of structural safety, fire safety, health and hygiene, and any further breakdown of these categories as appropriate.

(d) Determine how the hazard abatement code is enforced, and by what agency. Specify whether its enforcement is a function of geographical location within the community, and if so, specify how. Specify whether the code is enforced differently in different occupancies or types of buildings.

(e) Determine how the hazard abatement code's enforcement is triggered. Specify if it is triggered uniformly for all buildings or classes of buildings, or whether it is triggered by actions other than the mere presence of the hazard, such as application for a building permit.

(2) Building Maintenance Codes (Property Maintenance/Housing/ Health/Fire Prevention)

(a) Determine whether a housing code, property maintenance code, fire prevention code, health code, or any other regulation which may similarly cover the maintenance, operation and use of buildings, are in effect in the community. Some of these provisions may be part of building, mechanical, plumbing or electrical codes. For all such codes in effect, determine whether they include explicit criteria for various enforcement options by the authority having jurisdiction. Such criteria may be found in ancillary inspection manuals, or may be specified by reference to the building, mechanical, plumbing or electrical codes.

(b) Exhibit the criteria for various enforcement actions contained in these codes, in the categories of structural safety, fire safety, health and hygiene, and any further breakdown of these categories as appropriate.

(c) Determine how each of these maintenance codes is enforced, and by what agency. Specify whether each code's enforcement is a function of geographic location within the community (e.g., target neighborhoods for housing code enforcement). Specify whether each code's enforcement is varied as a function of occupancy or building type (e.g., active housing code enforcement in nursing homes, active fire prevention code enforcement in public assembly occupancies, etc.).

(d) Determine how the enforcement of each maintenance code is triggered.

Specify how violations of these codes are brought to the attention of the authorities, and whether the codes' enforcement is triggered uniformly for all buildings, classes of buildings, neighborhooods or similar classifications, or whether it is triggered by actions independent of the normal operation, maintenance and use of existing buildings, such as application for a building permit.

(3) Retroactive Regulations

(a) Identify all retroactive regulations currently applicable to existing buildings in the community.

(b) For each retroactive regulation, identify the unsafe or undesirable conditions which the regulation is intended to correct. Specify whether the regulation applies to all buildings, to specific occupancies or building types, or to any other limited category of buildings.

(c) For each regulation, determine the criteria which must be met for compliance. These criteria may be established by reference to the building code or some other code.

(d) Exhibit the criteria for compliance with each retroactive regulation in the categories of structural safety, fire safety, health and hygiene, as applicable.

(e) Determine how each retroactive regulation is enforced, and by what agency. Specify whether the enforcement is a function of geographic location within the community, or of any categorization of buildings (e.g., by occupancy, type, age, condition, etc.).

(f) Determine how the enforcement of each retroactive regulation is triggered. Specify how deficiencies are brought to the attention of the authorities. Determine whether the enforcement is triggered by actions which are independent of the presence of the specific deficiencies, such as application for a building permit.

A.2 Define New Construction Requirements and Their Enforcement

(a) Identify all existing codes currently applicable to new construction in the community. These may include a building code, mechanical code, plumbing code, electrical code, various specialty codes, life safety codes and special regulations. For each code, determine whether it is locally promulgated, or whether it is a statewide code. If it is the latter, determine whether it is mandatory minimum, maximum or both.

(b) Determine the occupancy and use categories into which buildings are classified by the codes. Determine fire districts, or other locational categories into which buildings are classified by the codes.

(c) For each building classification, determine the criteria which must be met for compliance.

(d) Categorize these criteria into the same, or similar categories to those utilized for displaying the criteria for the codes and regulations applicable to existing buildings as specified in the preceding section. Display the criteria in these categories to the extent and level of detail possible.

(e) Describe how the codes covering new construction are enforced, and by what agencies. Include in this description any cross referencing or interagency coordination employed in the enforcement. If code enforcement is carried out by various levels of government (state, county), it should be fully described. Determine the mechanisms for triggering code enforcement activities, such as application for building permits, mechanical permits, electrical permits, etc.

A.3 Define Provisions Covering Building Rehabilitation

(1) 25–50% Rule

(a) Determine whether the community's building code includes the 25–50% Rule or similar rule covering building repair and alteration. Determine whether a similar rule is included in the mechanical, plumbing and electrical codes.

(b) Determine how the building code addresses additions to existing buildings.

(c) If the 25–50% Rule, or similar rule, is in effect, determine the criteria that are required for compliance when rehabilitation work falls into each of the following three, or similar applicable categories:

- under 25%
- 25–50%
- over 50%

(d) Determine whether reference is made to any other codes (e.g., the code under which the building was originally built) in establishing these criteria.

(e) Display the criteria for compliance in the same categories as those utilized in the preceding section.

(f) If the 25–50% Rule, or similar rule, is in effect, determine how it is enforced. Specify how the value of the numerator (value of repair and alteration work) is determined in terms of work items covered and cost estimates. Specify how the value of the denominator (value of the existing building) is determined.

(g) Determine whether the 25–50% Rule is enforced uniformly for all buildings, or whether its enforcement differentiates between classes of buildings on any basis.

(h) Determine whether the 25–50% Rule discriminates against certain building owners or certain neighborhoods in the community, by resulting in the impostion of different criteria for similar rehabilitation of similar buildings.

(2) Change of Occupancy

(a) Determine the current regulation governing code compliance of existing buildings involved in a change of occupancy. Usually this regulation is part of the building code.

(b) Determine whether the change of occupancy regulation requires full compliance with all code requirements for new construction of the occupancy proposed, or whether only partial compliance is required. If partial compliance is included in the regulation, determine whether it is based on a systematic ordering of occupancies in terms of hazard, or on a similar defined analytical procedure.

(c) If partial compliance is included, determine the criteria which are established for each category of occupancy change, and display the criteria in the same categories as those utilized in the preceding section.

(d) Determine how the change of occupancy regulations are enforced, and whether they are enforced uniformly throughout the community.

(3) Other Rehabilitation Provisions

(a) Identify all other provisions which may affect building rehabilitation in the community. These may include landmark and historic district ordinance provisions, historic preservation waivers, regulation of moved buildings, general building rehabilitation provisions, etc. Some of these may be included in the building code, in ancillary inspection manuals or similar documents.

(b) Determine what criteria are specified for compliance with any such special provision, and display them in the same categories as those utilized in the preceding section.

(c) Determine how these special provisions are enforced, including use of advisory boards, review panels, appeals boards, etc.

A.4 Compare Criteria Levels

Compare the displays of the various sets of criteria included in all elements of the existing building regulatory system in the community which were defined and displayed under A.1–A.3 of this Part. This comparison may take the form (graphically or conceptually) of the conceptual diagram included in Part I of

this Guideline. In such an approach, the criteria for new construction are likely to define an upper limit of performance. The requirements imposed on existing buildings are likely to define a lower limit of performance. The existing regulations governing building rehabilitation will define where different categories of rehabilitation are required to fall between these two limits.

This comparison and display of criteria levels will identify for policymakers the extent of upgrading required for rehabilitated buildings by the existing regulatory system, and will enable them to determine whether this upgrading is consistent with local rehabilitation policies.

B. Define Pertinent Characteristics of Building Rehabilitation in the Community

Building rehabilitation in a community is a function of many factors, such as:

- physical characteristics of the community
- age and condition of the building stock
- economic conditions of development
- socio-economic conditions in the community
- regulatory system and its history
- public policy at the federal, state and local levels of government.

It is necessary to define the following pertinent aspects of building rehabilitation, and their relationship to some of these factors:

- Define occupancies involved or potentially involved in rehabilitation.
- Define building ages and types involved or potentially involved in rehabilitation.
- Determine extent of illegal rehabilitation.
- Define existing rehabilitation policies.

B.1 Define Occupancies Involved or Potentially Involved in Rehabilitation

Determine whether building rehabilitation in the community is principally a matter of upgrading or re-use of existing occupancies (e.g., residential rehabilitation, commercial rehabilitation, etc.), or whether it is a matter of changing occupancies (e.g., commercial to residential, residential to commercial, residential to assembly, etc.). This can be determined both by observing actual current rehabilitation projects, as well as by identifying potential candidates for rehabilitation (which due to existing problems or constraints may not be currently undergoing rehabilitation).

The nature of occupancy changes involved in rehabilitation is often related to the changing nature of neighborhoods and of the community as a whole, and is therefore subject to the economic conditions of development, socio-economic and physical characteristics of the community.

It is important to define the occupancies involved, or potentially involved in rehabilitation, because the building regulatory system is likely to treat rehabilitation involving occupancy change very differently from that in which no change is involved. In general, the former is likely to entail the enforcement of higher levels of performance in the rehabilitated building. For this reason it is also necessary to determine the extent to which the occupancy classifications contained in the community's building code (see A.2(b) of this Part I) correspond to, or fit with, the actual uses of buildings being rehabilitated. If this correspondence, or fit, is not clear, then the regulatory system will involve ambiguities in dealing with change of occupancy rehabilitation.

B.2 Define Building Age and Types Involved or Potentially Involved in Rehabilitation

Determine the age and principal characteristics (structural, architectural, mechanical) of buildings involved, or potentially involved in rehabilitation work in the community. This can be determined by both observing current projects as well as identifying potential candidates for rehabilitation.

While the age and principal characteristics of buildings are mainly a part of the general physical characteristics of the community, it must also be analyzed in relation to the history of the building regulatory system in the community. Such an analysis will determine the extent of the disparity between the characteristics and performance of the existing building stock and the current code requirements for new construction. For example, a community where most of the buildings are 25 years od, and where there have been very few code changes during that period, will have very different problems of regulation of rehabilitation than a community with buildings over 50 years old and with a history of numerous code changes. Washington, D.C. and San Francisco fall into the latter category, which may explain the specific nature of their regulatory approach to rehabilitation (as discussed in Part 1 of this Guideline).

B.3 Determine Extent of Illegal Rehabilitation

Illegal rehabilitation is the practice of carrying out repairs and alterations in buildings without the permits required for such work by a community's regulatory system. It is necessary to determine the extent and nature of such rehabilitation occurring in the community, and to identify the classes of building in which it is occurring, because this characteristic may indicate the effectiveness of the regulatory system in dealing with rehabilitation. The extent and nature of this phenomenon may also help in identifying potential problems of safety, health and hygiene which should be addressed by the regulatory system for rehabilitation.

B.4 Define Existing Rehabilitation Policy

Identify all the current policies related to building and neighborhood rehabilitation which are in effect in the community. These policies may be federal (expressed by the community's acceptance of federal assistance), state, local or neighborhood generated.

Specify the building classes or types which are addressed by the rehabilitation policy.

Attempt to determine the relative real costs which these rehabilitation policies intend for the community to bear. For example, how much, if any, relative safety, convenience and other features should the community be willing to give up in order to achieve the goals of the rehabilitation policies.

C. Identify Potential Problems

If the following conditions are found in the community, it could indicate problems in need of solution:

(1) *Conflict between the goals of rehabilitation and the goals of building regulation.* The health and safety goals of the building regulatory system are usually not made explicit in a community. However, the existence of the conflict between rehabilitation goals and regulation goals may be determined by the community if it finds that current building regulations impose unacceptable cost on rehabilitation and prevent much rehabilitation from taking place. The current regulations may impose these costs either by forcing the upgrading of rehabilitated buildings to levels of performance which are too high for the community, or by accepting only design solutions prescribed for new construction.

The community may also determine that such a conflict exists between rehabilitation and regulation goals when the enforcement of the regulations on existing buildings (hazard abatement codes, property maintenance codes and retroactive regulations) is triggered only by application for building permits. In this case the enforcement system is

discriminating against all rehabilitation activities of the community, by enforcing regulations that should apply to all existing buildings.

(2) *Discrimination of current rehabilitation regulations against a class of buildings or owners.* This condition may occur in a community which applies the 25–50% Rule to rehabilitation, as discussed above.

(3) *Violation of existing regulations.* The existence of extensive illegal rehabilitation work in the community, as discussed above, is evidence of this condition.

The above conditions may indicate the existence of one or more of the following four problems, listed in increasing order of the required modification to the regulatory system. Each problem is defined in PART III of this Guideline, where recommendations are made for solutions.

1. No modification in current regulatory system (25–50% rule and change of occupancy regulation) is needed.
2. Flexible application of the 25–50% rule is needed.
3. Existing regulatory system, in its relation to building rehabilitation, is in need of modification.
4. A definition of imminent hazards is needed in the regulatory system.

PART III—RECOMMENDATIONS FOR AMENDING OR MODIFYING THE REGULATORY SYSTEM TO ENCOURAGE REHABILITATION

A discussion of rehabilitation problems is contained in an article by William J. Tangye, P. E., entitled *"Rehabilitation of Existing Buildings An Achievable Goal"*, printed in Southern Building, February/March 1980. The article includes several recommendations, including proposed additions or amendments to the Standard Building Code, and is reprinted with the permission of the Southern Building Code Congress International, Inc., as Appendix 11 of this guideline.

The following recommendations are established for each of the four problems defined in the preceding part of this guideline. In general, a community will find that it is faced with one or more of these problems. All communities, however, should refer to the accompany *Statutory Guideline for Building Rehabilitation, Guideline for Managing Official Liability Associated with Building Rehabilitation,* and the *Guideline for the Approval of Building Rehabilitation* for recommendations which are consistent with all four problems.

Also, all communities should consider enacting historic preservation waiver clauses, if they have not already done so.

A community located in a state which has statewide preemptive codes may be constrained in carrying out some or all of the following recommendations. It should determine the extent of such constraints before attempting to amend or modify its regulatory system.

1. No modification in current regulatory system (25–50% rule and change of occupancy regulation) is needed.

Problem. The community determines that its current building code provisions applicable to rehabilitation, including the triggering of full code compliance by the 25–50% Rule and by the change of occupancy regulation, do not represent conflicts with rehabilitation goals, do not intentionally unduly constrain building rehabilitation and do not discriminate against classes of buildings or owners. Such a community accepts the impposition of new construction standards on much of its rehabilitation. Howevèr, the community determines that rehabilitation is unintentionally constrained by the prescriptive nature of many building code requirements.

Recommendations. The community should do the following:

(a) Explicitly justify, as a matter of public policy, each code requirement which is applied by current regulations to rehabilitated buildings, and which is in excess of the current requirements applicable to existing (unrehabilitated) buildings (e.g., hazard abatement code, property maintenance code and retroactive regulations).

(b) Amend the building code, electrical code, plumbing code, etc. to explicitly mention the acceptability of alternate materials, methods of construction and designs when dealing with buildings under the 25–50% Rule and with buildings undergoing a change of use or occupancy.

(c) Implement the following technical guidelines:

- *Egress Guideline for Residential Rehabilitation*
- *Electrical Guideline for Residential Rehabilitation*
- *Plumbing DWV Guideline for Residential Rehabilitation*

In general, each of these guidelines suggests alternative solutions recommended for building rehabilitation, which provide approximately equivalent performance as specified by current codes for new construction.

(d) Implement technical guidelines similar to those of (c) above, which may be developed and published from time to time, or develop and implement similar guidelines of its own.

2. Flexible application of the 25–50% rule is needed.

Problem. The community's current building regulations include the 25–50% Rule. The majority of building rehabilitation in the community does not involve a change in use or in occupancy. The community's goals are to encourage such rehabilitation, and the community is will to accept a level of performance for its rehabilitated buildings which is lower than that required for new construction. However, the 25–50% Rule as currently enforced requires full code compliance in more cases than the community finds appropriate and/or discriminates against classes of buildings or owners in the community.

Recommendations. The Community should consider the following:

(a) *Defining Cost and Value.* In any jurisdiction which has the 25–50% Rule and desires to interpret it so as to promote rehabilitation as much as possible, the objective is to obtain the lowest possible ratio of cost of rehabilitation (numerator) to the value of the building (denomination). The definition of cost, therefore, should be as low as possible. Based upon case studies the following methods of defining cost are either in use or suggested by building officials. Except where noted, these interpretations may be made by the building official without changing regulations.

(i) *Defining Cost of Rehabilitation (the numerator).*

Objective: Obtain Lowest Possible Value.

- Exclude all non-permit items such as painting and decorating, kitchen cabinets, landscaping, architect's fee and the like.
- Exclude all items which require a separate permit and which are normally covered by a separate code not governed by the 25–50% Rule, such as plumbing, electrical and elevator.

(ii) *Defining Value of the Building (the denominator).*

Objective: Obtain Highest Possible Value.

- Define value as current replacement cost before rehabilitation, and update at least annually.
- Define value as current replacement cost *after* rehabilitation. (This may not be feasible under the Standard Building Code since it requires the "then" physical value, presumably before rehabilitation. Also, the Basic Building Code implies replacement value before rehabilitation although this is not specifically stated.)
- Assessed value is reportedly used in some jurisdictions, but in general

assessed value lags behind true replacement value. In addition, assessing practices often assess various occupancies using different methods which could lead to discrimination.

(b) *Varying the Percentages.* Consider increasing the percentages (e.g., 33–66% instead of 25–50%). This will tend to allow more rehabilitation before encountering new construction code requirements. To implement this change, a code amendment is required.

(c) *Reducing the Time Span.* The model codes and most local codes require that for purposes of the 25–50% Rule cost be defined as work done within one year. Reducing the time span to six months, for example, would tend to allow phased upgrading of buildings. This change, also, requires a code amendment.

(d) Consider the use, or possible modification (to reflect acceptable lower levels of performance), of the technical Guidelines as suggested for the preceding problem.

3. Existing regulatory system, in its relation to building rehabilitation, is in need of modification.

Problem. The community determines that its current building regulations conflict with its rehabilitation goals by requiring upgrading of many or most of its rehabilitated buildings to the performance levels specified for new construction or even to some lower level, leading to unacceptably high costs of rehabilitation which unduly constrain building rehabilitation. Also, the community may determine that the regulatory system discriminates by enforcing existing building regulations in cases of rehabilitation only.

Recommendations. The community should do one of the following:

(a) Consider applying or adapting a current regulatory innovation; or

(b) Develop its own local rehabilitation code, provisions or guidelines.

(a) *Consider applying or adapting a current regulatory innovation.* Part I and the Appendix of this guideline contain discussions of various existing comprehensive or partial regulatory innovations. These include:

- Washington, D.C. (Appendix 2)
- San Francisco, California (Appendix 3)
- Denver, Colorado (Appendix 4)
- State of Massachusetts (Appendix 5)
- State of California (Appendix 6)
- City of Los Angeles Rule of General Application on Structural Changes Required by Change of Occupancy (Appendix 7)
- State of California Draft Legislation Related to Seismic Hazards (Appendix 8)
- Chapter 10, Official Electrical Code of the City of Detroit (Appendix 9)

The community faced with this problem may consider adopting or modifying one or more of these regulatory innovations. Such a community should do the following:

(i) Analyze each innovation in detail, from the materials appended to this guideline, and from additional materials obtained locally as required. This analysis should pay particular attention to the specific community characteristics (physical, social, economic, political, etc.) which led to the development of each regulation. Since each of the regulation examples was developed to respond to local community conditions and needs, a given community considering adopting such a developed regulation must be aware of the similarities and dissimilarities of its own community characteristics in relation to those of the model being analyzed. A level of performance acceptable in one community may not be acceptable in another.

Note that of the complete "solutions", Washington, D.C. and San Francisco use specific, and often prescriptive, provisions applicable to rehabilitation. These may have limited transferability to any but very similar cities. Denver provides a mechanism for dealing with every case individually, rather than establishing comprehensive provisions. Massachusetts uses an approach in which every building defines the level of performance to which it must be rehabilitated.

(ii) Based on the analysis, adopt and/or modify one of the model regulatory innovations.

(iii) Amend current codes appropriately, including deletion of the 25–50% Rule and/or the change of occupancy provisions. It must be realized that such deletions require the substitution of specific provisions. It should also be noted that by deleting the 25–50% Rule, a community may inadvertently have a deleterious effect on rehabilitation below 25%, which currently enjoys the continuation of non-conforming rights.

(iv) Consider the use, or possible modification (to reflect acceptable lower levels of performance), of the technical guidelines as suggested in the preceding problem.

(b) *Develop local rehabilitation code or guidelines.* If the community determines that none of the regulatory innovations are applicable, it should develop its own rehabilitation code, regulation or guidelines. It may proceed as follows:

(i) Determine the levels of performance required for all existing buildings by the current hazard abatement code, property maintenance code and retroactive regulations. As a minimum, all rehabilitated buildings must meet these levels. Note that in the absence of a current definition of "imminent hazard", the recommendations for Problem 4, below, should be followed.

(ii) If the community determines that higher levels of performance than those determined in (i) above are to be required for rehabilitated buildings (involving no occupancy change and/or involving change of occupancy), each such requirement should be individually justified, as a matter of public policy. The justification should cover structural safety, fire safety, health and hygiene.

(iii) Amend current codes appropriately, including deletion of the 25–50% Rule and/or the change of occupancy provisions. It must be realized that such deletions require the substitution of specific provisions. It should also be noted that by deleting the 25–50% Rule, a community may inadvertently have a deleterious effect on rehabilitation below 25%, which currently enjoys the continuation of non-conforming rights.

(iv) Consider the use, or possible modification (to reflect acceptable lower levels of performance), of the technical guidelines as suggested in the preceding problem.

A format and methodology for developing a local rehabilitation code, based on comparative analysis of rehabilitation needs with the code requirements for new construction, is presented in Appendix 10 of this guideline.

4. A definition of imminent hazards is needed in the regulatory system.

Problem. The community may have a need to define "imminent hazard". For a community facing any of the preceding three problems, the problem may be its desire but inability to establish compliance priorities for any level of performance.

For a community facing problem categories 2 or 3 above (i.e., considering acceptance of lower levels of performance for rehabilitated buildings), the problem may be the inability to establish the absolute lowest acceptable level of performance by requiring only the elimination of "imminent hazards" as a requirement attending rehabilitation.

Recommendations. To assist the community in assessing an "imminent

hazard", the following attributes and criteria should be considered:

(a) *Structural Safety.* A building presents an imminent hazard:

(1) Whenever the stress in any materials, member or portion thereof, due to all dead and live loads, is more than one and one-half times the working stress or stresses allowed in the code for new buildings of similar structure, purpose or location.

(2) Whenever any portion thereof has been damaged by fire, earthquake, wind, flood or by any other cause to such an extent that the structural strength or stability thereof is materially less than it was before such catastrophe and is less than the minimum requirements of the code for new buildings of a similar structure, purpose or location.

(3) Whenever any portion or member or appurtenance thereof is likely to fail, or to become detached or dislodged, or to collapse and thereby injure persons or damage property.

(4) Whenever any portion of a building, or any member, appurtenance, or ornamentation on the exterior thereof is not of sufficient strength or stability, or is not so anchored, attached or fastened in place as to be capable of resisting a wind pressure of one-half of that specified in the code for new buildings of similar structure, purpose or location without exceeding the working stresses permitted in the code for such buildings.

(5) Whenever any portion thereof has racked, warped, buckled or settled to such an extent that walls or other structural portions have materially less resistance to winds or earthquakes than is required in the case of similar new construction.

(6) Whenever the building or structure or any portion thereof because of: a) dilapidation, deterioration or decay; b) faulty construction; c) the removal, movement or instability of any portion of the ground necessary for the purpose of supporting such buildings; d) the deterioration, decay or inadequacy of its foundation; or e) any other cause, is likely to partially or completely collapse.

(7) Whenever the exterior walls or other vertical structural members list, lean or buckle to such an extent that a plumb line passing through the center of gravity does not fall inside the middle one-third of the base.

(b) *Number of Exits.* A building presents an imminent hazard whenever less than two approved independent exitways serve every story (except as modified for single exitways by current building codes or by the accompanying *Egress Guideline for Residential Rehabilitation*).

(c) *Capacity of Exits.* A building presents an imminent hazard whenever any required door, aisle, passageway, stairway or other required means of egress is insufficient to comply with the current code section on exit capacity or is so arranged as to preclude safe and adequate means of egress (see *Egress Guideline for Residential Rehabilitation*).

(d) *Other.* A building presents an imminent hazard whenever conditions exist which in the code official's judgment would be cause for an otherwise fully code-complying building to be evacuated or padlocked, or for the site or other adjacent areas to be evacuated, barricaded or otherwise protected.

Appendix 3—San Francisco, California

San Francisco, Calif.

The following concepts are involved in San Francisco's approach to regulating rehabilitation:

(a) *Residential Buildings (SFHC).*

1. Limiting areas of concern. (Section 105 and 309 SPHC)

2. Providing less strict construction standards, than for new construction, for areas of concern.

3. Providing a legal means for developing and implementing regulations "supplemental to this code and not in conflict therewith." this enables the creation of FIM. (Section 104 (f) SFHC and 204.2 SFBC)

4. Developing a manual (FIM) based upon commonly found conditions so as to provide both equity and uniform enforcement of alternatives and interpretations.

(b) *Change in Use or Occupancy (SFBC).*

The SFBC criteria primarily relate to the degree to which the proposed change may generate additional public hazard (Sections 104.E–3, 502.1(e), SFBC). The SFBC requires changes involving large public assemblies, schools and hospitals to virtually fully meet the present standards. It does not require this for most changes involving commercial or residential usage. These more common changes, as well as all others, are subject to one of three levels of possible building code application, indicated in Table No. 5.1, SFBC. This Table was developed based upon an evaluation of the potential increase or decrease in public safety from fire, panic and other hazards that may result from the proposed change.

These three levels are: (See Table No. 5.1 SFBC footnotes)

Level 'P'—This level requires only that the exists, ventilation, sanitation and fire fighting elements meet the SFBC. Seismic upgrading, per Section 104.F SFBC only applies when the occupant or floor load increases (e.g., a warehouse change to office building, or a garage converted to a heavy manufacturing plant), provided however that no seismic upgrading is required per Section 104.E–3 SFBC unless the change involves more than 30% of the building area. This latter provision was added so as to avoid minor changes causing extensive or costly work on the building.

Level 'PS'—This level requires that specific evaluation of the proposed change be made by the Bureaus of Building Inspection and Fire Prevention so as to determine what other SFBC provisions (other than those required for Level 'P') may be required to adequately protect the public.

"Blank" Space—This level requires that the change must fully meet the present SFBC requirements since the hazard level increases warrants such compliance for public safety.

(c) *Alterations, Additions and Extensions (SFBC)*

1. When substantially the entire interior of the building undergoes change ("gut job"), it is anticipated that there will be sufficient funds involved to warrant invoking seismic upgrading requirements for public safety. (Section 104.C–4, SFBC).

2. When virtually all walls are undergoing change (75% or more) all remaining walls on the floor involved have to be also upgraded. This is also based on the substantial financial involvement. (Section 104.C–3, SFBC).

3. When more than 30% of the building is involved in structural changes, the seismic provisions of Section 104.F, SFBC are invoked. (Section 104.B–3, SFBC).

Following are the pertinent sections of the San Francisco Building Code (SFBC) and Housing Code (SFHC).

San Francisco Building Code

Sec. 104A. Application to Existing Buildings, General. Buildings or structures to which additions, alterations, or repairs are made, or in which the occupancy of all or a portion of the building is to change from that for which a permit has been issued, shall comply with all requirements for new buildings or structures except as specifically provided in Sections 104.A through 104.H and as required in the Housing Code.

→The term "portion of the building" shall mean the floor or floors that are affected by the change in use.

Notarized certifications describing the extent of all previous substantial alteration work and/or previous changes of occupancy shall be

submitted by the owner and the designer of a proposed alteration or change of occupancy when required by the Superintendent.←

For construction in Fire Zones, see Article 16.

Sec. 104.B Alteration Work, Structural. In any alteration, repair, installations, or change or reconstruction of any building, the new work and any part of the building which becomes an integral part of, or is directly affected by such work, shall meet the structural requirements of this Code, →for vertical loads.

For the purpose of this section, a floor of a building shall include all the structure supporting a level of the building between the underside of said structure and the underside of the structure supporting the level of the building next above.

The extent of an existing building that is considered as being directly affected by the new work, with regard to structural considerations, shall be determined using the following criteria:

1. When structural alteration work is to be done on a floor or floors of a building or structure, the work on the floor or floors involved shall comply with the structural requirements of this Code. The structure above and below the floor or floors involved shall be improved, if and as required, so that they are not adversely affected by the structural work proposed.

2. When the floor loading is increased on the floor or floors of a building or structure, the floor or floors involved shall meet the structural requirements of this code and all structure below the floor or floors with increased loading shall not be adversely affected.

3. When more than 30%, cumulative since the building was built, of the above grade area of the building or structure are involved in substantial structural alteration work, the entire building or structure shall comply with the structural requirements of Section 104.F.←

Sec. 104.C. Alteration Work, Architectural. In any alteration, repair, installation, or change in or reconstruction of any building, the new work and any part of the building which becomes an integral part of, or is directly affected by the new work, shall meet the requirements of the Code.

The extent of an existing building that is considered as being directly affected by the new architectural alteration work shall be determined, using the following criteria in addition to the provisions of Section 502.1:

1. All new work added to the building that did not previously exist in the building.

2. All portions of the building that are removed and replaced by new construction.

3. When 75% of the existing interior walls or partitions, as measured by the lineal footage of such interior wall and partition, are removed on a floor or when new interior walls or partitions are added which exceed 75% of the total lineal footage of the combined existing and new interior walls and partitions that would then be in place on a floor, all interior walls and partitions on the floor involved shall comply with this Code.

→4. Whenever alteration work involves extensive changes to elements such as walls, partitions, ceilings, etc. in substantially all portions of such structure, the structure as a whole shall comply with Section 104.F.←

→Sec. 104.D. Additions to Buildings. 1. Vertical Extensions. Buildings may be extended vertically subject to the following requirements:

a. Building shall be used for the same occupancy classification as originally built or for less hazardous occupancy classification as determined from Table No. 5–1. The occupancy of the vertical extension shall comply with the requirements of this Code.

b. Way of departure facilities for the entire structure shall be of sufficient width for the total occupancy load of the building, including the vertical extension, and shall be computed on the basis of occupant loads as assigned in the code in effect at time of the original building erection.

c. All new construction work involved in the vertical extension shall conform to the requirements of this code.

d. The structure as a whole shall comply with Section 104.F.

e. All stairways in the building serving 3 or more stories shall be enclosed.

f. For height and area limitations see Article 5.

g. The original building and the vertical extension shall comply with the applicable provisions of Article 38.

2. Horizontal Extensions

a. Building may be used for higher life safety exposure, provided the structure as a whole meets the requirements in this code for such occupancy.

b. See Subsection 1(b).

c. See subsection 1(c).

d. When the cumulative area of additions above grade exceeds 30% of the above grade area of the original building and the additions are structurally interconnected to or inadequately separated from the original building, the entire structure shall comply with Section 104.F.

e. See Subsecton 1 (e).

f. See Subsection 1 (f).

g. See Subsection 1 (g).←

→Sec. 104.E. Change of Occupancy. The exit requirements shall pertain solely to the corridors and vertical enclosures of the floor or floors affected by the change in use, which requirements shall also include the vertical enclosure for the floor next above the affected floor or floors. This exit requirement shall not include the corridors and vertical enclosures for the floors below the affected floor or floors or the corridors above the effected floor or floors, except as otherwise stated herein.

1. Where a change in occupancy classification is proposed, the requirements of Table No. 5–1 shall apply.

2. When the change in use involves an increase in the occupant load of the floor or floors affected or when the change involves Occupancies A, B, C, D and E, the exit requirements shall include the vertical enclosures in accordance with Article 33 from the floor or floors in question to the ground at a street or public space. The exit requirements shall include the corridors of the floor or floors affected by the change in use and shall not include the corridors for the floors above or below the affected floor or floors.

3. Whenever the cumulative areas involved in change of occupancy to a greater life safety exposure from that for which the building was originally designed exceed 30% of the original above grade area of the building, the entire building shall be made to comply with Section 104.F.

Exceptions. When the occupancy change is to a Group A, B Div. 1 or B Div. 2 classification and Group B Div. 3 classification with an occupant load over 300, the entire building shall be made to comply with Section 104.F.

2. When the occupancy change is to a Group C classification the entire building shall be made to comply with the requirements of footnote 1 of Table No. 5.1 as well as the Sec. 104.F.←

BILLING CODE 4210-01-M

TABLE NO. 5.1

OCCUPANCY CHANGES PERMISSIBLE WITHOUT CONFORMING TO ALL PROVISIONS OF PRESENT CODE

From \ To	OCCUPANCY GROUP																		
	A	B-1	B-2	B-3	C[1]	D-1	D-2	D-3	E-1	E-2	E-3	E-4	F-1[2]	F-2	F-3	G	H	I	J-1
A	P	P	P	P	P		PS	PS					PS	P	PS	PS		PS	P
B-1	PS	P	PS	P	P		PS	PS					PS	P	PS	PS		PS	P
B-2	PS	PS	P	P	P		PS	PS					PS	P		PS		PS	P
B-3				P	P		PS	PS					PS	P		PS		PS	P
C				PS	P	PS	PS	PS					PS	P		PS	PS	PS	P
D-1				PS		P							PS	P		PS	PS	PS	P
D-2				PS	P		P	P					PS	P		PS	PS	PS	P
D-3				PS	P			P					PS	P		PS	PS	P	P
E-1									P	P	P					PS		PS	P
E-2									PS	P	P	P	PS			PS		PS	P
E-3									P	PS	P		PS			PS		PS	P
E-4												P	PS			PS		PS	P
F-1													P	P		PS		PS	P
F-2					PS			PS					PS	P		PS	PS	PS	P
F-3													PS	PS	P	PS			P
G												PS			PS	P			P
H				PS	PS	PS	PS	PS						P		PS	P	P	P
I					PS									PS			PS	P	P
J-1																			P

LEGEND for Table No. 5.1

P — Occupancy change permitted subject to the requirements of Sections 502.1 and 1706.A, except for ducts, Tables No. 5-C, 5-D, and 5-E, and Article 38.

PS — Occupancy change permitted subject to requirements as set forth by the Superintendent, and the Bureau of Fire Prevention and Public Safety for those occupancies under their jurisdiction.

Where square is blank, change in occupancy requires substantial conformance with all present code provisions.

[1] Shall require conformance with Article 23 for seismic provisions. Same as used by State OAC. [2] Not including service stations and gasoline filling stations.

BILLING CODE 4210-01-C

TABLE NO. 5

OCCUPANCY CLASSIFICATIONS

Group or Class	Division	Description of Occupancy	Article Reference
A		Any assembly building with a stage and an occupant load of 1000 or more	6
B	1	Any assembly building with a stage and an occupant load of less than 1000	7
	2	Any assembly building without a stage and with occupant load of 1000 or more	
	3	Any assembly building without a stage and with occupant load of less than 1000	
	4	Stadiums, reviewing stands and amusement park structures not included in Group A nor Group B, Division 1, 2, and 3 Occupancies	
C		Any building used for school purposes involving assemblage for instruction, education or recreation	8
D	1	Jails, prisons, reformatories, houses of correction and buildings where personal liberties of inmates are similarly restrained, mental hospitals	9
	2	Nurseries for children under six, kindergartens, orphanages, hospitals, sanitoriums, nursing homes and similar buildings (each accommodating more than 6 persons) with non-ambulatory patients	
	3	Nursing homes for ambulatory patients, homes for children of kindergarten age or over (each accommodating more than 6 persons not including employees)	
E	1	Manufacture, storage and handling of hazardous and highly flammable or explosive gases, liquids and materials other than flammable liquids	10
	2	Storage and handling of flammable liquids	
	3	Shops and factories where loose combustible fibers or dust is manufactured, processed, or generated. Warehouses where loose combustible material is stored	
	4	Public repair garages. Heliports. Storage and parking garage for trucks and buses	
F	1	Gasoline filling and service stations, factories and workshops using material not highly flammable or combustible, large garment shops. Furniture warehouses and similar not more hazardous warehouses	11
	2	Wholesale and retail stores, office buildings, printing plants, municipal police and fire stations, public assembly with an occupant load of less than 50, small garment shops, paint stores without bulk handling, day care of children	
	3	Public Parking Structures and storage garages Type A—Drive-in Type B—Mechanical parking Type C— →Drive-in or←Mechanical parking—Type 4 construction	
G		Ice plants, power plants, pumping plants, cold storage and creameries. Factories and workshops using incombustible and non-explosive materials. Storage and salesrooms for incombustible and non-explosive materials	12
H		Hotel, motels, and apartment houses; dormitories for more than six persons in aggregate; convents, monasteries and rectories each containing six or more sleeping rooms	13
I		One and two family dwellings and lodging houses	14
J	1	Private garages, Sheds and minor buildings used as accessories, fences over six feet high, tanks and towers	15
	2	Stables	

→Sec. 104.F. Lateral Force Design Requirements. The provisions of Sec. 2308 and Sec. 2314.D through .H shall apply to the entire building or structure. It shall be demonstrated that the entire building or structure is capable of resisting these forces and safeguarding the occupants and the public.

Consideraton shall be given to all aspects of construction which may affect safety; including but not necessarily limited to the adequacy of connections between structural members, the adequacy of building separation and the security of unreinforced filler walls as well as parapets and appendages.←

Sec. 204.2 Director may adopt Rules and Regulations. The Director of Public Works may adopt and promulgate rules and regulations supplemental to this Code and not in conflict with the intent therewith. → Such rules and regulations shall be generally accepted or approved methods and practices for the public health and welfare and safety of life, subject to re-examination and change if at any time such rules and regulations are found to be not in conformance with the intent or requirements of the Municipal Code.

The Director may administratively authorize the processing of applications involving Housing Code compliance actions initiated by the Department of Public Works, in a manner other than set forth in this Code, so as to effect said compliance most expeditiously; provided however that due process is assured all applicants. In this regard, the Director may reduce the time periods set forth in Sections 301.C.e, 302.D and 302.D.2 as they apply to a second application required by the Director to effect full compliance with the Housing Code if by so doing compliance with the Housing Code would be more expeditiously accomplished.

Sec. 502.1. Minimum Requirements Applicable for Change of Occupancy. In addition to the requirements of Tables No. 5-D and 5-E, and the specific requirements of the new occupancy as set forth in Articles 6 through 15, where the change of occupancy is permissable under Table No. 5.1, the following requirements shall in all cases be met for the new occupancy in compliance with this Code:

(a) Exit requirements per Article 33 to the public way

(b) Ventilation

(c) Sanitation

(d) Fire extinguishing equipment and protection devices per Article 38.

(e) Lateral force provisions of Section 104.F, if the change of occupancy results in an increased occupant load or floor load.

San Francisco Housing Code

Section 104. Scope.

(f) It is further provided that the Director of Public Works may adopt and promulgate rules and regulations supplemental to this Code and not in conflict therewith, provided they are the most generally accepted or approved methods and practices for public welfare and safety of life and property. Such rules and regulations shall be subject to reexamination and change if at any time such rules and regulations are found by any enforcement agency not to be in conformance with the intent or requirements of the Municipal Code

Sec. 105. Existing Buildings. All buildings erected after July 26, 1958 shall comply either with the codes in effect at the time of construction or the present Building, Electrical, and Plumbing Codes at the discretion of the owner.

All buildings erected prior to July 26, 1958 shall comply with the requirements as set forth in the codes in effect at the time of construction except as otherwise provided herein. The retroactive provisions in Article 3 shall take precedence over any Code provision in effect at the time of construction.

All buildings altered or converted prior to July 26, 1958 which do not conform to the codes in effect at the time of the alteration or conversion and the provisions of this Code shall be reconverted back to the original approved state and brought into compliance with the retroactive requirements applicable to the original structure, or conform to all the applicable requirements outlined in the present codes.

Sec. 801. Ways of Departure. See Articles 1, 13 and 14 of the Building Code.

Way of departure facilities for buildings constructed, altered or converted after July 26, 1958 shall comply with the codes in effect at the time of construction, alteration or conversion, or the provisions of Section 3302.A.1, 3320 and 3320.1 of the Building Code, whichever is the less restrictive, as is applicable to that occupancy.

Way of departure facilities for buildings constructed, altered, or converted prior to July 26, 1958 shall meet the following minimum requirements or the provisions of Sections 3302.A.1, 3320 and 3320.1 of the Building Code, whichever is the less restrictive.

Each of the following buildings, now in existence shall be provided with access for each dwelling unit or guest room to two means of egress which shall be accessible either directly or through a public hallway and shall be so located that if access to one be denied, the other shall be available:

(1) In apartment houses, hotels (and two-family dwellings per Section 3320.1 of the Building Code.).

Where exits are arranged so that one way of departure must be passed to get to the other, intervening doorways between any exit doorway on a dead end corridor more than 20 feet in depth and the main exit corridor shall be provided with a ¾-hour opening protector or a sprinkler head located on the room side of the doorways as well as in the dead end corridor.

(2) Every single family dwelling having more than two floors of occupancy in which there are rental units, shall have not less than two ways of departure from the uppermost stories to a floor of occupancy below which has two ways of departure to the exterior of the building.

Sec. 807. Smoke Barriers. In buildings in which an existing Group H occupancy is located on three or more stories and which does not have a way of departure directly accessible from within each apartment or guest room without entering an exit corridor, every interior public stairway shall be enclosed as set forth in Section 806 of this Code or shall be provided with a smoke barrier and smoke stop door, as hereinafter described, to prevent fire and smoke from spreading, thereby cutting off the way of departure.

An automatic sprinkler system installed in an exit corridor and stairwell and exitway to exterior of building, in accordance with the provisions of Article 38 of the Building Code, will be acceptable in lieu of a smoke barrier.

When a hotel room or apartment opens directly upon the stairway so that the smoke barrier does not afford said room or apartment protection, said hotel room or apartment shall have a one and three-eighths inch solid core wood door, an incombustible surfaced door or other similar approved self-closing device.

The smoke barrier and smoke stop door shall be located where directed by the Superintendent and shall be constructed as follows:

(1) In Type 3 and 5 buildings, the smoke barrier may consist of partitions containing wire glass with solid core wood smoke stop doors. The doors shall be not less than one and three-eighths inch thick, three feet wide, and six feet eight inches high equipped with an approved self-closing device. The smoke barrier may be of any approved similar construction except that wood panels and similar combustible materials shall not be permitted.

(2) In other than Type 3 and 5 buildings, the smoke barrier partitions shall be entirely of incombustible construction except for the smoke stop door and the trim and except that wire glass lights in the partition shall be permitted. The smoke stop door may be an unrated, solid-core wood door not less than one and three-eighths inch thick, three feet in width and six feet eight inches in height equipped with an approved self-closing device and may have wire glass lights therein.

Smoke barrier doors may be held in an open position to allow for the necessary corridor ventilation, provided the means of holding the doors open include a smoke detection device and a

SAN FRANCISCO FIELD INSPECTION MANUAL FOR EXISTING RESIDENTIAL BUILDINGS

Introduction

This manual is to be used as a guide for inspection of residential buildings built prior to July 26, 1958 in determining whether the building is substandard as defined in Article 4 of the 1975 San Francisco Housing Code. This manual does not pertain to non-residential buildings or occupancies except in the case of a mixed occupancy building, then only as violations affect the residential occupancy.

The retroactive provisions of the Housing Code are to be applied to all buildings whenever built, altered, or inspected. See Section 309 of the Housing Code for the list of retroactive sections.

If a requirement other than those retroactive is neglected on permit work done within the last twenty years, it should be provided only when a most serious hazard would result from its absence. The following shall be used as examples of a most serious hazard, but is not intended to be all inclusive: unsafe or obstructed egress; an excess floor of occupancy exists; substantial structural inadequacy exists caused by sagging or deteriorated structural members, or the absence of lateral supports; lack of light and ventilation, the absence of toilet or bath facilities within the dwelling unit, substantial overloading of electrical service or exposed wiring; lack of sprinkler system where required.

If a building was built or converted before twenty years ago under a permit, but some code requirements were neglected, they must be provided if their absence constitutes a *hazard*, including those listed above.

If a building was built or altered without a permit, it must meet the Code standards of the day of its construction or alteration as modified herein, and as provided in the retroactive section of the Housing Code.

Appendix 6—State of California

Revision Record for Register 78, No. 26 (July 1, 1978)

TITLE 25. HOUSING AND COMMUNITY DEVELOPMENT

Part I. Housing and Community Development

Chapter 1. State Housing Law Regulations and Earthquake Protection Law Regulations

Subchapter 1. State Housing Law Regulations

Article 6. Rehabilitation and Repair of Existing Buildings

70. Rehabilitation. Any portion of an existing structure which is subject to the provisions of this subchapter may be altered, repaired or rehabilitated, regardless of the value of the work or the duration of construction period, without the entire structure being made to comply with the requirements of this subchapter for new construction.

72. Plumbing. (a) Any plumbing system may have its existing use, maintenance or repair continued if the use, maintenance or repair is in accordance with the original design and location and no hazard to the public health, safety or welfare has been created by such system. (17922(c) Health and Safety Code, effective date January 1, 1975)

(b) Alterations. In existing buildings or premises in which plumbing installations are to be altered, repaired or renovated, the enforcement agency has discretionary powers to permit deviation from the provisions of this subchapter, provided that such a proposal to deviate is first submitted to the enforcement agency for proper determination in order that health and safety requirements as they pertain to plumbing shall be observed. (17922(c) Health and Safety Code, effective date January 1, 1975)

(c) Building Sewers. Existing building sewers and building drains may be used in connection with plumbing alterations or repairs if such sewers or drains have been properly maintained and were installed in accordance with the applicable laws in effect at the time of installation. (17922(c) Health and Safety code, effective date January 1, 1975)

(d) Existing Plumbing Systems. Any plumbing system shall be deemed to have conformed to applicable law in effect at the time of installation and to have been maintained in good condition if currently in good and safe condition and working properly. (17922(c) Health and Safety Code, effective date January 1, 1975)

74. Mechanical Equipment. Existing mechanical equipment may be used in connection with alterations or repairs if such mechanical equipment has been properly maintained and was installed in accordance with the applicable laws in effect at the time of installation. Any mechanical equipment in existence shall be deemed to have conformed to applicable law in effect at the time of installation and to have been maintained in good condition if currently in good and safe condition and working properly. (17922(c) Health and Safety Code, effective date January 1, 1975)

Except as otherwise noted in Section 17922(c) Health and Safety Code, all alterations, repairs, or additions of mechanical equipment shall conform to Section 48 of this subchapter.

76. Electrical Equipment. Existing electrical systems may be used in connection with alterations or repairs if such electrical systems have been properly maintained and were installed in accordance with the applicable laws in effect at the time of installation. Any electrical system in existence shall be deemed to have conformed to applicable law in effect at the time of installation and to have been maintained in good condition if currently in good and safe condition and working properly.

Alterations, repairs, or additions of electrical equipment shall conform to Section 50 of this subchapter.

78. Regulations for Existing and Relocated Buildings. Regulations governing the alteration and repair of existing and relocated buildings shall be as set forth in Sections 17958.8 and 17958.9 of the Health and Safety Code which reads as follows:

17958.8. HSC. Local ordinances or regulations governing alterations and repair of existing buildings shall, after July 1, 1975, permit the replacement, retention and extension of original materials and the use of original methods of construction as long as the hotel, lodginghouse, motel, apartment house or dwelling, or portions thereof, or building and structure accessory thereto, complies with the rules and regulations of the commission or alternative local standards adopted pursuant to Section 17920.7 and does not become or continue to be a substandard building. (Added Stats. 1974, c. 1268)

17958.9. Local ordinances or regulations governing the moving of apartment houses and dwellings shall, after July 1, 1978, permit the retention of existing materials and methods of construction so long as the apartment

house or dwelling complies with the rules and regulations of the commission or alternative local standards adopted pursuant to Section 17920.7, complies with the standards for foundation applicable to new construction, and does not become or continue to be a substandard building.

Article 7. Structural Fire Safety in Existing Buildings

80. (a) Authority. This article is adopted pursuant to the provisions of Section 17920.7 of the Health and Safety Code.

(b) Purpose. The purpose of these regulations is to provide a reasonable degree of safety to the occupants and the general public in existing multiple-story structures let for human habitation.

82. Application and Scope. Except as otherwise provided in Section 17920.7 of the Health and Safety Code and this subchapter, the provisions of this article shall apply to all existing multiple-story structures let for human habitation including, and limited to, apartment houses, hotels, and motels wherein rooms used for sleeping are let above the ground floor.

84. High Rise Structures. The provisions of this article shall not apply to any existing apartment house, hotel or motel having floors (as measured from the top of the floor surface) used for human occupancy located more than 75 feet above the lowest floor level having building access which is subject to the provisions of Sections B1733 through B1747, Part 2, Title 24, California Administrative Code relating to existing high rise buildings. (T25-84)

86. Inspection of Existing Buildings. The enforcement agency shall inspect every building reported to be in violation of this article, and in addition shall inspect buildings when deemed appropriate to obtain compliance with the regulations. A building which does not comply with the provisions of this article shall be declared to be a substandard building. The enforcement agency shall institute abatement proceedings to correct or abate a substandard building in accordance with the provisions of Section 114 to 144 inclusive of this subchapter.

88. Number of Exits. Every apartment and every other sleeping room shall have access to not less than two exits. A fire escape may be used as one means of egress, if the pitch does not exceed 60 degrees, the width is not less than eighteen inches (18"), the treads are not less than four inches (4") wide and they extend to the ground or are provided with counterbalanced stairs reaching to the ground. Access shall be by an opening having a minimum dimension of twenty-nine inches (29") with open. The sill shall not be more than thirty inches (30") above the floor and landing. (T25-88)

90. Stair Construction. All stairs shall have a minimum run of nine inches (9") and a maximum rise of eight inches (8") and a minimum width exclusive of handrails of thirty inches (30"). Every stairway shall have at least one handrail. A landing having a minimum horizontal dimension of thirty inches (30") shall be provided at each point of access to the stairway. (T25-90).

92. Interior Stairways. Except as provided herein, every interior stairway shall be enclosed with walls of not less than one-hour fire-resistive construction.

Where existing partitions form part of a stairwell enclosure, wood lath and plaster in good condition will be acceptable in lieu of one-hour fire-resistive construction. Doors to such enclosures shall be protected by a self-closing door equivalent to a solid wood door not less than one and three-fourths inches (1¾") thick. Enclosures shall include landings between flights and any corridors, passageways, or public rooms necessary for continuous exit to the exterior of the building.

The stairway need not be enclosed in a continuous shaft if cut off at each story by the fire-resistive construction required by this Subsection for stairway enclosures.

Enclosures shall not be required if an automatic fire-extinguishing system is provided for all portions of the building except bedrooms, apartments, and rooms accessory thereto.

Interior stairs and vertical openings need not be enclosed in two-story buildings. (T25-92)

94. Exterior Stairway. Existing exterior stairs of noncombustible materials or of wood not less than two-inch (2") nominal thickness with solid treads and risers may be continued in use provided they are properly maintained. (T25-94)

96. Existing Circular Stairways. Existing circular stairways may be used as an exit when adequately maintained and providing the minimum width of run is not less than 10 inches, and the smaller radius is not less than twice the width of the stairway. The width of treads and height of risers within any flight shall have identical dimension with a ¼ inch tolerance. (T25-96)

98. Existing Winding Stairways. Existing private winding stairways may be used when adequately maintained, provided the required width of run is provided at a point not more than 12 inches from the side of the stairway where the treads are the narrower, but in no case shall any width of run be less than 6 inches at any point. (T25-98)

100. Doors and Openings. Exit doors shall swing in the direction of exit travel, shall be self-closing, and shall be openable from the inside without the use of key or any special knowledge or effort. Doors shall not reduce the required width of stairway more than six inches (6") when open. Transoms, and openings other than doors, from corridors to rooms shall be fixed closed and shall be covered with a minimum of three-fourths inch (¾") plywood or ½ inch gypsum wallboard or equivalent material. (T25-100)

102. Swing. Exit doors shall swing in the direction of exit travel when serving any hazardous area or when serving an occupant load of 50 or more. Double acting doors shall not be used as exists serving a tributary occupant load of more than 100; nor shall they be used as a part of a fire assembly, nor equipped with panic hardware. A double acting door shall be provided with a view panel of not less than 200 square inches. (T25-102)

104. Exit Signs. Every exit doorway or change of direction of a corridor shall be marked with a well-lighted exit sign having letters at least 5 inches high. This section shall apply only when the occupant load is in excess of 50 (T25-104)

106. Enclosure of Vertical Openings. Elevators, shafts, ducts, and other vertical openings shall be enclosed as required for stairways in Section 96, or by wired glass set in metal frames. Doors shall be noncombustible, or as regulated in Section 96. (T25-106)

108. Separation of Occupancies. (a) Occupancy separations shall be provided as specified in this subchapter. Lobbies, and public dining rooms not including cocktail lounges, shall not require a separation if the kitchen is so separated from the dining room. Boiler rooms or heater rooms containing a central heating plant using solid or liquid fuel shall be separated from the rest of the building by a One-Hour Fire-Resistive Occupancy Separation.

(b) **Equivalent Protection.** In lieu of separation of occupancies required by Subsection (a), equivalent protection may be permitted when approved by the enforcement agency. (T25-108)

110. Portable Fire Extinguishers. Portable fire extinguishers shall be provided and maintained in every apartment house and hotel in accordance with requirements set forth in this article.

112. Number and Type. The number and type of portable fire extinguishers to be installed shall be determined by the enforcement agency. However, the

minimum requirements shall be as set forth in Title 19, Chapter 1, Subchapter 3, California Administrative Code.

Note. See Section 17920.7, of the Health and Safety Code, which in pertinent part reads: ". . . It is the intention of the Legislature that this section and the rules and regulations adopted by the commission pursuant to this section shall not be more restrictive than the requirements for new construction contained in the Uniform Building Code . . ."

Therefore this article is not applicable to two-story buildings with an occupant load of no more than 10 above ground floor. (See Uniform Building Code, Paragraph 3302(a) 1970 Edition.)

Appendix A. Health and Safety Code Division 13. Part 1.5 State Housing Law

Chapter 1. General Provisions

17912. Rules and regulations promulgated pursuant to the provisions of this part, relating to the erection or construction of buildings or structures, shall not apply to existing buildings or structures or to buildings or structures as to which construction is commenced or approved prior to the effective date of the rules or regulations, except by act of the Legislature, but regulations relating to use, maintenance, and change of occupancy shall apply to all hotels, motels, lodginghouses, apartment houses, and dwellings, or portions thereof and buildings and structures accessory thereto, approved for construction or constructed before or after the effective date of such rules or regulations. (Amended Stats. 1974, c. 1268)

Chapter 2. Rules and Regulations

17920. As used in this part:

(f) "Substandard building" means any building or any portion of a building including, but not limited to, any dwelling unit, guest room, or suite of rooms, or the premises on which the same is located, in which there exist any of the conditions listed in Chapter 10 of the Uniform Housing Code, latest edition, including inadequate structural resistance to horizontal forces, to an extent that endangers the life, limb, health, property, safety, or welfare of the public or the occupants thereof.

However, a condition which would require displacement of sound walls or ceilings to meet height, length, or width requirements or ceilings, rooms, and dwelling units shall not by itself be considered sufficient existence of dangerous conditions making a building a substandard building, unless the building was contructed, altered, or converted in violation of such requirements in effect at the time of construction, alteration, or conversion.

Any wiring, plumbing, or mechanical equipment, including vents, shall be deemed to have conformed to applicable law in effect at the time of installation and to have been maintained in good condition if currently in good and safe condition and working properly.

17920.6. As used in this part, "housing appeals board" means the board or agency of a city or county which is authorized by the governing body of the city or country to hear appeals regarding the requirements of the city or county relating to the use, maintenance, and change of occupancy of hotels, motels, lodginghouses, apartment houses, and dwellings, or portions thereof, and buildings and structures accessory thereto, including requirements governing alteration, additions, repair, demolition, and moving of such buildings if also authorized to hear such appeals. In any area in which there is not such a board or agency, "housing appeals board" means the local appeals board having jurisdiction over such area.

17920.7. (a) The commission shall adopt, amend, repeal, and except as otherwise provided in this part, enforce rules and regulations for the provision of structural fire safety and fire-resistant exists in existing multiple-story structures let for human habitation including, and limited to, apartment houses, hotels and motels wherein rooms used for sleeping are let above the ground floor. The rules and regulations shall provide adequate safety to the occupants and the general public, and shall impose the same requirements as are contained in subdivisions (d), (e), (f), (g), (h), (i), (k), and (l) of Section 1313 of Chapter 13 of the appendix of the Uniform Building Code, 1970 edition, as adopted by the International Conference of Building Officials.

The commission, after consultation with the State Fire Marshal, may adopt reasonable exceptions to subdivisions (e) and (g) of Section 1313 to permit the continued use of existing stairs and to subdivision (l) of Section 1313 to permit equivalent protection in lieu of occupancy separations. However, such exceptions shall not impair occupant safety and shall be consistent with the legislative intent of this section.

Interior stairs and vertical openings need not be enclosed in two story buildings.

(b) Notwithstanding the provisions of subdivision (a), any city, county, or city and county may adopt standards for structural fire safety and fire-resistent exists in structures subject to the provisions of this section, provided that such standards are substantially equivalent in fire safety to the standards adopted by the commission pursuant to subdivision (a). Each city, county, or city and county adoping such alternative standards shall submit a detailed statement, with supporting data, to the Director of Housing and Community Development demonstrating the equivalency of the alternate standards. The Director of Housing and Community Development shall make a finding as to the equivalency of alternate local standards to state standards. It is the intention of the legislature that this section and the rules and regulations adopted by the commission pursuant to this section shall not be more restrictive than the requirement for new construction contained in the Uniform Building Code, 1970 edition, as adopted by the International Conference of Building Officials.

17921. The commission shall adopt, amend, repeal, and, except as hereinafter provided, the department shall enforce rules and regulations for the protection of the public health, safety, and general welfare of the occupant and the public governing the erection, construction, enlargement, conversion, alteration, repair, moving, removal, demolition, occupancy, use, height, court, area, sanitation, ventilation and maintenance of all hotels, motels, lodging houses, apartment houses, and dwellings, and buildings and structures accessory thereto. Such rules and regulations may include a schedule of fees to pay the cost of enforcement by the department under Sections 17952 and 17965. (Amended Stats. 1974, c 1268)

17922. (c) Regulations governing alteration and repair of existing buildings and moving of apartment houses and dwellings shall permit the replacement, retention, and extension of original materials and the continued use of original methods of construction as long as the hotel, lodging house, motel, apartment house, or dwelling, or portions thereof or building and structure accessory thereto, complies with the rules and regulations of the commission or alternative local standards adopted pursuant to Section 17920.7 and does not become or continue to be a substandard building. Building additions or alterations which increase the area, volume, or size of an existing building, and foundations for apartment houses and dwellings moved, shall comply with the requirements specified in this part, or in rules and regulations adopted pursuant to this part, for new buildings or structures. However, such

additions and alterations shall not cause the building to exceed area or height limitations applicable to new construction.

Chapter 4. Application and Scope

17958.8. Local ordinances or regulations governing alterations and repair of existing buildings shall, after July 1, 1975, permit the replacement, retention and extension of original materials and the use of original methods of construction as long as the hotel, lodging house, motel, apartment house or dwelling, or portions thereof, or building and structure accessory thereto, complies with the rules and regulations of the commission or alternative local standards adopted pursuant to Section 17920.7 and does not become or continue to be a substandard building. (Added Stats. 1974, c. 1268)

17958.9. Local ordinances or regulations governing the moving of apartment houses and dwellings shall, after July 1, 1978, permit the retention of existing materials and methods of construction so long as the apartment house or dwelling complies with the rules and regulations of the commission or alternative local standards adopted pursuant to Section 17920.7, complies with the standards for foundation applicable to new construction, and does not become or continue to be a substandard building.

APPENDIX 11

Southern Building Magazine, February/March 1980; "Rehabilitation of Existing Buildings: An Achievable Goal" by William J. Tangye, P.E.

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Rehabilitation of Existing Buildings: An Achievable Goal

The cover of this issue of the "Southern Building" magazine acknowledges 40 years of service by the Southern Building Code Congress to the building community. During these 40 years the south in particular and the nation in general have undergone a tremendous building boom, the results of which are the existing buildings of today that form one of our most important, yet least recognized, resources.

It seems appropriate, therefore, to reflect upon both the code requirements of the past 40 years and those existing buildings that were designed and constructed to meet those requirements. It is recognized that these existing buildings may not comply with all the requirements of today's codes, yet, at the time of their construction, they complied with the applicable codes and standards and in most cases have stood the test of time by serving their intended use in a safe and satisfactory manner.

The fact that these buildings, for the most part, have performed their intended function is sufficient to justify their rehabilitation and/or reuse. It is imperative—if we are to achieve the goal of rehabilitating our existing building stock—that a concerted effort be made by code enforcement personnel, local governments and others involved in the building community to encourage and find the means to facilitate this activity.

Codes and Enforcement Today

Today's codes and code enforcement techniques are being criticized in the belief that both impede if not discourage the rehabilitation of existing buildings. Much of this criticism is not valid. There are some aspects, however, that ring true and these aspects should be considered by us as a challenge to prove that rehabilitation of existing buildings can be accomplished in a timely and beneficial manner using the present codes enforcement process. The accomplishment of this challenge may require modifications to both codes and enforcement techniques but more important, it will require a change in attitudes about building rehabilitation.

In order to adapt a code enforcement program to include the rehabilitation of existing buildings, we need to briefly review how the present system works.

Applicable Building Regulations

Existing buildings are, in general, regulated by one of the following methods:

1. Standard Building Code—Sections 101.4(a) through (d) covers existing buildings that are to be altered or repaired or that have been damaged, but the occupancy classification of the rehabilitated building will not be changed. The requirements contained in these sections are commonly referred to as the 25–50% rule. Section 101.4(e) covers existing buildings that undergo a change in occupancy classification.

2. Standard Code for the Elimination or Repair of Unsafe Buildings—This code deals with existing buildings that represent an imminent hazard to life as defined in Section 201.3. This code is "building" rather than "occupancy" oriented and mandates that unsafe conditions be abated or that the building be demolished.

3. Standard Housing Code—This code deals only with existing Group R—residential occupancies and focuses primarily on health and safety issues and contains requirements aimed at maintaining the buildings in a habitable condition. It should be noted that the requirements in the housing code may be less than those required in new building construction.

4. Standard Fire Prevention Code—This code deals primarily with the maintenance of the life safety features of a building such as means of egress, fire protection systems, alarm systems and the handling and storage of hazardous or flammable materials. This code applies to all occupancy classification.

The above codes, with the exception of the Standard Building Code, deal with the maintenance of existing buildings in a safe and healthful manner and generally promote the continued use of our existing building stock. The Standard Building Code, on the other hand, is primarily directed toward new construction and even though it contains performance language such as Section 103.6—Alternate Materials and Alternate Methods of Construction, it also contains requirements such as those in Section 101.4 that may not in all cases encourage the rehabilitation of existing buildings.

It is my opinion that relatively few and minor changes would have to be made to the Standard Building Code to facilitate the rehabilitation of existing buildings. Accordingly, the remainder of this article will deal one with the Standard Building Code.

Before discussing modifications to the Standard Building Code, it should be emphasized that rehabilitation of existing buildings falls into two distinct categories. The first category includes existing buildings that are to be altered or repaired but in which no change of occupancy classification is contemplated. The second category contemplates that an existing building will undergo a change in occupancy classification.

These categories also comprise the two major criticisms of today's building codes relative to rehabilitation of existing buildings—the 25–50% rule and the categorical requirement that when the occupancy classification of an existing building is changed, the building must be made to conform to the code requirements for the new occupancy classification.

The 25–50% Rule

Let's consider first the 25–50% rule which is contained in Sections 101.4(a) thru (d) of the Standard Building Code and requires the following:

1. If an existing building is to be repaired or altered and the cost of such work done in any 12 month period exceeds 50% of the value of the building, the entire building must be brought up to current code requirements.

2. If an existing building is to be altered or repaired and the cost of such work done in any 12 month period is more than 25% but less than 50% of the value of the building, the building official must determine to what extent the building must be brought up to current code requirements.

3. If an existing building is to be altered or repaired and the cost of such work done in any 12 month period is less than 25% of the value of the building, the building need not be brought up to current code requirements.

4. If an existing building is damaged and the damage exceeds 50% of the value of the building, the building must be brought up to current code requirements. it is implied though not expressly stated that if the damage is less than 50%, the stipulations of items 2 and 3 above would apply.

The strict application of these requirements may discourage the rehabilitation of existing buildings for the following reasons:

1. There is no clear and concise definition of how to establish or what should be considered when established—the value of a building.

2. The percentages are arbitrary and have no basis in fact, thus making them difficult to enforce, particularly if court action is involved.

3. The value of a building will vary with not only the more traditional considerations of size, type of materials, occupancy, etc. but with the geographical location within a governmental jurisdictions boundaries, thus making the requirements potentially discriminating.

Deleting the Rule

Based on the preceding discussion one might conclude that the deletion of the 25–50% rule is the only answer to achieve the goal of rehabilitation of existing buildings. This is one alternative, but such radical action may not be necessary. If, for instance, the 25–50% rule were deleted in favor of some other wording, those buildings that presently fall in the category of less than 25% of the value of the building and are not required to meet the current code, would then have to comply with the new wording. It has not been shown that the "less than 25%" figure has resulted in unsafe buildings, neither has it been a deterrent to rehabilitation. The criticism has been with the higher percentages and the accompanying requirement for full or partial compliance with current code requirements. Therefore, deleting the rule would penalize a certain percentage of rehabilitation work now being accomplished. Another alternative might be to revise the percentage to say 33–66% to permit more rehabilitation work without having to comply with current code requirements. However, this is nothing more than juggling numbers and the new numbers have no more basis in fact than the old numbers. It might also be appropriate to reduce the time span from 12 months to 6 months, which would permit twice the amount of rehabilitation work before triggering compliance with current code requirements. A final alternative would be to remove the requirement for having to bring the entire building up to current code requirements and give the building official the authority to determine which requirements apply.

If a community chooses to maintain the 25–50%, which can be a viable option, the following are recommendations for modification to the rule that will encourage rehabilitation:

General Recommendations

1. Encourage a flexible interpretation of the rule.

2. Define the cost of rehabilitation to exclude all non-permit items such as painting, decorating, cabinets, land-scaping, kitchen and domestic appliances, architects, engineers or contractors fees and all items that would require a separate permit such as plumbing, mechanical and electrical.

3. Define the building value as the current replacement cost after rehabilitation. Do not use assessed valuation since it is usually out of date and may not reflect accurate replacement costs.

4. Revise time span to 6 months.

Specific Recommendations

1. Add a new definition to Section 201.2 to read as follows: COST OF REPAIR, ALTERATIONS OR REHABILITATION, means the cost of repairs, alterations or rehabilitation as used in Section 101.4 and shall include only those items that are regulated by this code and shall not include non-permit items such as painting, decorating, cabinets, land-scaping, appliances not regulated by this code, architects, engineers or contractors fees, nor shall it include items that require a separate permit such as plumbing, mechanical or electrical work.

2. Delete present definition of valuation or value and substitute the following: BUILDING VALUE, means the current replacement cost of a building after repair, alteration or rehabilitation.

3. Delete Sections 101.4 (a) thru (d) and substitute the following: 101.4—EXISTING BUILDINGS (a) If, within any six(6) month period, alterations, repairs or rehabilitation work costing in excess of fifty (50) percent of the building value is made to an existing building, such alterations, repairs or rehabilitation work and the remaining portions of the building shall be made to conform to the requirements of this code for new construction to such extent as may be determined by the building official. (b) If within any six (6) month period, alterations, repairs or rehabilitation work costing in excess of twenty-five (25) percent but not more than fifty (50) percent of the building value is made to an existing building only the portions that are altered, repaired or rehabilitated shall be made to conform to the requirements of this code for new construction, to such extent as may be determined by the building official. (c) Buildings damaged by fire or other causes, and that are to be repaired or rehabilitated shall comply with the provisions of Section 101.4 (a) and (b). (d) The building value shall be established by the building official.

If a local government felt that the 25–50% rule in either its present state or as modified above was not adequate to encourage rehabilitation of existing buildings, the following wording could be used:

Delete present Sections 101.4 (a) thru (d) and substitute the following: 101.4—EXISTING BUILDINGS (a) Alterations, repairs or rehabilitation work may be made to any existing building without requiring the building to comply with all the requirements of this code provided that the alteration, repair or rehabilitation work conforms to the requirements of this code for new construction. The building official shall determine, subject to appeal to the Board of Adjustments and Appeals, the extent if any to which the existing building shall be made to conform to the requirements of this code for new construction. (b) Alterations, repairs or rehabilitation work shall not cause an existing building to become safe as defined in Section 103.4.

This latter type of wording is more broad in scope and will encourage rehabilitation work. However, it would be emphasized that if this course of action is taken, it will require that the owner, his architect or engineer and the code enforcement personnel work closely from project inception to completion to assure that all work will provide the necessary degree of life safety. Under this type of procedure, as well as any other involving the rehabilitation of existing buildings, all parties are encouraged to seek innovative solutions to code related issues. The key is not that the solution comply with the exact code wording but

rather that it achieve a level of safety consistent with that implied by the code.

Change in Occupancy

Consider Section 101.4(e) of the Standard Building Code which deals with changes in occupancy classification of existing buildings. This section requires that any time the occupancy classification of an existing building is changed, the building must be made to conform to the current code requirements for the new occupancy. It is obvious that this type of requirement poses a real roadblock to rehabilitation of existing buildings. Such compliance may not even be attainable considering that specific code language and the cost of attaining compliance, if possible, is often prohibitive. As a result, the rehabilitation work is done illegally or it is not done at all. Consequently, a building may be undesirable or, in the worst case, abandoned.

One of the arguments in favor of this type of specific wording is that if we do not require compliance with the current code when a change of occupancy classification is planned, we are establishing a double standard for existing and new construction. The concern of establishing a double standard is valid but can be resolved to the benefit of all of the local government wants to make the rehabilitation of existing buildings a reality. If we consider that modern building codes reflect the state of the art in building construction, new buildings constructed today should reflect this technology to insure that it is made available to the public. This is not to imply, however, that existing buildings lawfully occupied but not meeting the specific requirements of the current code are less than safe. These existing buildings, as discussed earlier, were built to some code or standard that reflected the state of the art at the time. If they have performed their intended use without exposing the public to any undue hazard, one must conclude that they are safe even though they may not in all respects comply with current codes. This is not consistent to require compliance with current code requirements in order to rehabilitate an existing building even though a change in occupancy classification may be involved. Further, not requiring compliance with current codes is not establishing a double standard but is instead recognizing the life safety required by past codes.

A point that should be made is that an existing building that is lawfully occupied may remain in its present condition and occupancy even though it does not comply with current codes for that occupancy. This is called a "non-conforming right". The occupancy of this building is contingent upon the assumption that there are no imminent hazards in the building. Even if there were hazardous conditions, the code only requires that the hazards be removed but does not require that the building be brought into compliance with the current code.

What the Standard Building Code is trying to accomplish in a change of occupancy classification in an existing building is to provide the equivalent level of health and safety to that prescribed for new construction. To accomplish this task, code enforcement personnel must research the intent of the various code requirements, not just rely on the specific wording. Alternate solutions and innovative methods to meet this intent in existing buildings can then be developed.

Thus, it can be seen that we are not dealing with a double standard, but simply more than one way to achieve the code goal of safety. We do much the same thing on new buildings. If an alternate solution to a specific code requirement is proposed that will achieve an equivalent level of safety to that specified, it can be approved under Section 103.6. If the concept is valid for new buildings, it is equally valid for existing buildings.

The concept of dealing with existing buildings undergoing a change in occupancy classification, and not requiring that the building be brought into compliance with current code requirements, will require that each building be individually evaluated by the code enforcement personnel to determine those areas of the building that need to be modified. It then becomes the responsibility of the owner or his agent to develop methods of accomplishing the modification within the framework of the building and the level of safety required. This process is shown graphically in Figure 1.

In order for this type of system to work, several things must be done other than a change in code wording. Perhaps the most important item is that the local government must be totally committed to the system. The local government should reflect its commitment by adopting a statement that could read as follows:

1. "The (legislative body) finds that the public health, safety and welfare is in part dependent on the conservation, rehabilitation and reuse of the existing building stock, including both residential and other buildings; that the strict application of new construction requirements and standards to the rehabilitation of existing buildings undergoing a change in occupancy may not result in the most timely and beneficial results; that rehabilitation is a major mechanism for increasing the health and safety in existing buildings; and that adequate resources in the form of public and private initiatives exist to increase and expand the incidence of rehabilitation.

"It is therefore the intent of this legislative body, to the maximum extent consistent with minimum standards of human health and safety.

"(1) to promote the rehabilitation of existing buildings by allowing for differences between rehabilitation and new construction in the application of the requirements and standards of this code as long as the equivalent level of safety can be achieved;

"(2) to encourage in rehabilitation the utilization of innovative and economical materials and methods of construction, to provide the level of safety; and,

"(3) to encourage the agencies charged with enforcement of codes, and the officers thereof,

"(i) to apply the provisions of the code to rehabilitated buildings in a manner consistent with the purposes stated herein; and,

"(ii) to exercise discretion and employ resourcefulness in the evaluation of code compliance of rehabilitated structures, in a manner consistent with the purposes stated herein."

In addition to the policy statement, the local governing body needs to be aware of the fact that there are no easy rules to follow in developing or approving innovative solutions to code intent and that disagreement may arise as to the most desirable course of action even when all parties are following the policy statement. Accordingly, it is advisable to establish a rehabilitation advisory board to review the methods and solutions proposed and to determine which course of action should be approved. This responsibility can be assigned to the board of adjustments and appeals which most local jurisdictions already have in existence.

It is imperative also that the local governing body provide protection for the code enforcement personnel from legal action that may arise out of the enforcement of rehabilitation concepts. Since a program, as outlined above, must deal in generalities rather than specifics, as the code does for new construction, this protection is absolutely necessary to free the code enforcement personnel from personal liability.

Recommendation

1. Adopt an ordinance or add to the building code a section to read as follows:

"All officers and employees of (the state, or local jurisdiction, as applicable) charged with enforcement of) state or municipal law generally, or specifically enumerated laws such as building codes) shall be relieved of all personal liability for all damage that may accrue to persons or property and for all costs, including attorney's fees, reasonably necessary to defend against litigation resulting from any act required or permitted in the discharge of official duties and exercised in good faith without malice or intentional wrongdoing. Pursuant to this section, the (jurisdiction) may purchase insurance to indemnify itself, its officers, and its employees from legal liability and defense costs. If insurance is not purchased or available, a suit instituted against an officer or employee for conduct arising out of the lawful discharge of official duties shall be defended by the (legal representative of the jurisdiction, e.g., city attorney) until the final termination of the proceedings, and the (jurisdiction) shall be liable for all costs reasonably necessary to defend such action and for all resulting judgments against the officers and employees based on the good faith discharge of said official duties."

The last item to be accomplished is a modification to Section 101.4(e) that will provide the building official with the authority to approve alternate solutions to code requirements when a change of occupancy classification to an existing building is contemplated.

Recommendation

Delete Section 101.4(e) and substitute the following:

(e) If the occupancy classification of an existing building is changed, the building shall be made to conform to the intent of this code for the new occupancy classification as established by the building official.

Once the changes to the code text as outlined for the 25–50% rule and the change in occupancy have been made and the policy statement and legal statement adopted, the basic framework for a workable rehabilitation program is in place.

The actual rehabilitation of an existing building is not a simple task and will require careful study and application of code intent. There are no manuals or books that will provide acceptable alternate solutions or tradeoffs to every code item and, as such, these solutions will have to be developed as they arise on an individual basis by each code enforcement agency.

There is, however, some valuable information contained in the "Draft Rehabilitation Guidelines" published by the Department of HUD, in the Federal Register, Vol. 44, No. 215, Monday, November 5, 1979. This document, which was prepared in part by the model code groups, has been prepared as a voluntary guideline to be used by local governments in rehabilitation programs and certain information in this article was drawn from it. Copies may be obtained by writing the Dept. of HUD, Division of Energy, Building Technology and Standards, Room 8164, Washington, D.C. 20410.

There are also several cities that have implemented rehabilitation programs. These include Los Angeles, California; San Francisco, California; Denver, Colorado; and Washington, D.C. Copies of these programs should be requested from the building departments in each city. Also, the SBCCI is preparing a manual for code enforcement personnel involved in the inspection of existing buildings for rehabilitation. The manual will contain a discussion of general considerations and more specific sections on materials, construction methods, equipment and planning factors and will include possible corrective measures. For more information on the Rehab Inspection Manual, contact Bill Manning, P. E. or Al Moffitt, R. A. at the SBCCI headquarters.

The SBCCI Technical Department will provide plan examination service on existing buildings that are to be rehabilitated. This review service will be provided for active members and each such review must be accompanied by a letter of authorization from the active member, a copy of the plans, a description of all work to be done to the building, its intended occupancy, structural calculations and a copy of the building department's inspection report on the building. For more information on this service, contact W. J. Tangye, P. E. at the SBCCI headquarters.

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Guideline for Approval of Building Rehabilitation

Introduction

Most communities have laws, regulations and codes which govern the construction and use of buildings. This

regulatory system involves an approval process which consists of three distinct functions:

- Construction permits (prior to construction)
- Construction inspections (during construction)
- Maintenance inspections (throughout a building's life)

This process is used to regulate both new building construction and rehabilitation of existing buildings. In the case of rehabilitation, where parts of an existing building remain, the first two functions (construction permits and construction inspections) often involve delays, additional paper work, cost increases and other adverse effects, because of problems such as the following:

- characteristics of existing materials or equipment (e.g., strength, capacity, etc.) cannot always be determined accurately;
- materials, equipment or methods of construction may be concealed from view and cannot be determined except by partial demolition;
- the size (e.g., height, width, thickness, length or shape) or location of existing building parts which are to remain may preclude design or construction solutions specifically covered by codes or regulations; and
- complete designs or accurate scopes-of-work cannot always be made prior to the start of construction.

The new construction approval process is well known to everyone in the industry, and it functions efficiently. For rehabilitation, however, it is less well known and it functions less efficiently. This guideline is intended to assist communities in improving the rehabilitation approval process.

To fulfill this intent, the following portion of the guideline has been organized according to the functioning of the approval process, in five sequential steps:

Step 1. Outreach Program
Step 2. Preliminary Review
Step 3. Construction Permits
Step 4. Construction Inspections
Step 5. Maintenance Inspections

The discussion of steps 2 through 5 compares rehabilitation to new building construction to emphasize the special considerations for rehabilitation and to facilitate rehabilitation by suggesting improvements in its approval process.

Step 1. Outreach Program

An outreach program which clearly explains a community's approach to rehabilitation helps design professionals, contractors and building owners. It may also help code enforcement personnel, since those whom they serve will be better informed. While outreach is not strictly a part of an approval process, it is an essential part of a comprehensive regulatory program to encourage rehabilitation.

A rehabilitation outreach program should have two basic interrelated features:

- providing building owners, design professionals and contractors with information about rehabilitation and its approval process, and
- making those authorities having jurisdiction over a rehabilitation approval process more accessible to building owners, design professionals and contractors.

A program of information dissemination might use any one or combination of the following opportunities in conjunction with improved access to rehabilitation authorities:

- radio or television "spot" announcements;
- newspaper advertisements;
- adult education and professional continuing education courses, workshops and conferences; and
- free literature at banks, libraries, government offices and "do-it-yourself", lumber and hardware stores.

Portland, Oregon, for example, has used television "spot" announcements effectively.

An outreach rehabilitation program should provide information regarding:

- permits required, and how, when, and where to obtain them;
- technical requirements and regulations governing rehabilitation;
- necessary construction inspections, and when they must occur;
- related regulatory and procedural matters; and
- how, when and where to obtain more information.

Increased accessibility to the authorities having jurisdiction over the rehabilitation approval process is not only a means to help those interested in rehabilitation to secure information more easily, but it is also a means to improve the rehabilitation process itself. A community might use any one or combination of the following opportunities:

- assign one or more regulatory personnel to handle all rehabilitation projects;
- locate all code permit functions in one office space or building when multiple permits are required;
- issue one permit instead of multiple permits;
- use neighborhood offices rather than a central office for the approval process;
- hold open houses at the authorities' offices; and
- extend the hours of the authorities' office operation to evenings and Saturdays so as to be more accessible to homeowners.

Seattle, Washington, for example, has assigned one plan check engineer to handle all rehabilitation; and this, it is felt, provides continuity, familiarity with problems unique to rehabilitation and a reduction in the number of formal appeals. Portland, Oregon, has instituted a regularly scheduled "homeowners' evening" at the building department to improve accessibility.

An effective rehabilitation outreach program facilitates the subsequent steps of the approval process.

Recommendation

Develop a rehabilitation outreach program related to the community's approval process, and specifically designed to meet its needs.

Step 2. Preliminary Review

New Buildings

Preliminary reviews are becoming more widely accepted by communities. They are the real first step in the approval process for new building projects, and consist of an examination with the authorities having jurisdiction of the design, construction and codes issues related to those projects. It may be a formal, official review or an informal, unofficial one. As preparation for the mandatory steps following, this step should be taken at the earliest possible time, and should involve all the authorities in a community concerned with a project. Its aim is to get the project started "on the right foot".

Some authorities having jurisdiction are not the least reluctant to participate on- or off-the-record in the preliminary review of projects. They recognize that in the next steps of the approval process their participation is mandatory. These authorities understand that the purpose of this initial step is to solve potential problems before they become real problems and to expedite the approval process, thereby reducing delays, paperwork and costs.

For new building construction, the preliminary review is usually a meeting (or a series of meetings on larger and more complex projects). Preferably, the meeting will include not just the building department but all the jurisdictional bodies concerned with a project (e.g., planning, zoning, design review, historic preservation, fire health, traffic, etc.).

In Bloomington, Minnesota, for example, the Fire and Life Safety Committee meets on a regular schedule and has members from every concerned jurisdictional body. The committee participates in formal preliminary reviews of all projects.

At the conclusion of the preliminary review, a general and clear understanding about the following is usually established:

- code applicability to a proposed new building's use and occupancy with regard to existing site conditions and proposed building plan layouts, heights, areas, materials, equipment and construction methods;
- mandatory inspections;
- permit fee schedules;
- forms and applications which must be obtained from all the concerned jurisdictional bodies; and
- possible items of non-compliance with the codes for which a modification may need to be sought now or in the construction permit step through the formal appeals process (see *Statutory Guideline for Building Rehabilitation).*

Usually, only very preliminary drawings and outline specifications are necessary for a preliminary review. Even concept drawings, rough sketches and material lists may be enough for simple buildings. For industrialized buildings, producers' literature may provide adequate information.

Rehabilitation

Preliminary review for rehabilitation projects is much the same as that for new construction, but there are important differences in its purpose, and in the way its procedures should be implemented.

In addition to expediting the approval process and solving potential problems before they become real ones, the preliminary review for rehabilitation has three purposes:

- to establish or clarify an owner's intent and proposed scope-of-work (e.g., change of occupancy, change of use, extent of construction, etc.), in order to clarify the code implications of the program;
- to determine the specific applicable code requirements and whether in fact pemits are needed; and
- to establish an acceptable rehabilitation program, including the definition of any alternative or equivalent design or construction solutions to code requirements which may be necessary.

If an owner has enough information about the building to be rehabilitated, a preliminary review may only require a single meeting. In larger, more complex projects or when necessary information is not available at the first meeting, two or more meetings may be required.

In the latter circumstance, necessary information should be obtained by either the first or both of the following investigation procedures:

- a search by jurisdiction personnel of the records of all the jurisdictional bodies concerned with the past and present occupancy of the building to be rehabilitated; and
- an on-site investigation of the existing building by qualified jurisdiction personnel or by private engineers and architects.

An on-site investigation of an existing building may consist of any one or combination of the following:

- an assessment of the physical context of a building to determine the acceptability of some proposed rehabilitation solutions such as those suggested in the *Plumbing DWV Guideline for Residental Rehabilitation* (e.g., single stack DWV solutions are not recommended for use where a sewer system is subject to flooding) or the *Egress Guideline for Residential Rehabilitation* (e.g., certain egress solutions may depend upon accessibility of the building to the fire department);
- a determination by observation of such physical conditions of an existing building as structural integrity, electrical equipment damage, the number of electrical receptacle outlets or the number of stories, suites, rooms or exits;
- a determination by measurement and/or calculation (which may in some cases require selected demolition; see Step 3. Construction Permits of this guideline) of such physical characteristics of an existing building as area, height, plumbing DWV piping sizes, electical conductor sizes, electrical load-carrying capacity, sizes of structural members, composition of fire resistant assemblies and fire resistance ratings, or widths and lengths of exitways;
- a determination by testing of the adequacy of function or performance level of such parts of an existing building as plumbing DWV piping, electrical equipment and devices, or archaic materials and assemblies for fire resistance.

See the *Electrical Guideline for Residential Rehabilitation,* the *Plumbing DWV Guideline for Residential Rehabilitation,* the *Egress Guideline for Residential Rehabilitation* and the *Guideline on Fire Ratings of Archaic Materials and Assemblies* for more detailed discussions of on-site investigation methods.

It is important to note that any imminent hazard found in the investigation should be reported to the authority having jurisdiction for enforcement of applicable regulations.

When the investigation has obtained all the necessary information, a second preliminary review meeting (or series of meetings if required) can take place. The understandings reached and the conclusions made at the end of this step for rehabilitation concern the same subjects as those for new building construction. However, in those jurisdictions which issue construction permits, it may be concluded that unlike new construction, some rehabilitation projects do not require construction premits. This decision by an authority having jurisdiction will take into account such factors as the quantity of rehabilitation work, the safety and health implications of the work, and whether a change of occupancy or use is involved.

Many rehabilitation projects will require essentially the same types of drawings, sketches, specifications or material lists as new building construction. In some instances, one line diagrams or system schematics will be necessary for testing during a field investigation (see the *Plumbing DWV Guideline for Residential Rehabilitation*) 1or for clarifying existing conditions. For simpler or less extensive rehabilitation, a written description of the scope-of-work may be all that is necessary.

Recommendations

- Initiate a Preliminary Review step for rehabilitation, or modify the current Preliminary Review procedure used for new buildings.
- Develop on-site investigation procedures for existing buildings which are based on the nature of the community's building stock.

Step 3. *Construction Permits*

New Buildings

There are three basic types of construction permits for new buildings, used for three distinct circumstances:

- a Full Pemit is used when there is enough information about the total scope of a project's work;
- a Partial Permit is used in some communities when there is enough information about only a part of the total scope of a project's work; and
- a Conditional Permit is used in some communities when there is not enough information to issue a Full or Partial Permit, but construction can begin

safely on a portion of the work and can be completed when the mission information is determined and formally approved.

New building construction may have a series of Partial Permits (e.g., excavation, foundations, superstructure, sewer hook-up, etc.) which together equal a Full Permit when the last Partial Permit is issued. Partial Permits necessitate a series of permit applications, plan reviews, and permit issuances. The total of Partial Permit fees usually exceeds the fee for a Full Permit.

Permit application and issuance is a formal, official step in the approval process which is carred out under the auspices of the authorities having jurisdiction. For the construction permit, it consists of three stages:

- a formal application to the authorities having jurisdiction;
- a formal plan review of the construction permit application, and approvals by other jurisdictional bodies (e.g., zoning board, health department, etc.) if required; and
- the issuance or "filing" of the construction permit(s) upon approval of the application.

In new building construction, the construction documents needed for the application and plan review usually consist of detailed construction drawings (working drawings) and specifications. Approval of these construction documents in the plan review may be withheld if some portion of the proposed work is not in compliance with the applicable code(s), or if the construction documents are inadequate in some way.

In the case of non-compliance, an applicant can either change the proposed work to comply or choose to seek modification of the code(s) through the formal appeals process.

If the construction documents are inadequate, an applicant should make the necessary changes or additions to them.

A properly executed Step 2 (Preliminary Review) should reduce problems in this step to a minimum, and expedite the issuance of the construction permit(s).

With the filing of the construction permit(s), construction may begin.

Rehabilitation

For rehabilitation, the construction permit process is generally the same as that for new construction. There are, however, some aspects of rehabilitation which may be different from new construction, and some aspects of the appoval process which may be improved to better serve rehabilitation:

- *Construction Documents*—In some instances, rehabilitation construction documents may not need to be as extensive or detailed as those required for new construction. It may be possible in some communities for less complex projects to use a written description of materials and equipment as construction documents, and where necessary to supplement this with one-line diagrams, sketches or product literature.
- *Partial Permits*—1In some communities, Partial Permits may not be in common use, or may not be permitted. However, because their use is expecially suited to the rehabilitation of selected parts of an existing building (e.g., electrical system, plumbing system, etc.), the use of Partial Permits should be considered. The higher fee for multiple Partial Permits (as compared to a Full Permit fee) may be a constraint to rehabilitation which communities can modify.
- *Conditional Permits*—In rehabilitation, Conditional Permits are particularly useful to allow that selected demolition necessary for the exploration of concealed construction to determined the condition and adequacy of existing materials, equipment and installation methods as preparation for establishing a rehabilitation scope-of-work (see Step 2. Preliminary Review).
- *Preliminary Review*—The findings from a Preliminary Review may be even more important to rehabilitation than to new building design and construction. These findings should be fully and carefully incorporated into the application for the permit(s) as a means to reduce delays in this step and in the Construction Inspection step following.

Recommendations

- Amend the community's Construction Permit procedures and related fee structures, to utilize Partial Permits and Conditional Permits as needed to accommodate the needs of rehabilitation.
- Establish construction document requirements appropriate to rehabilitation.
- Develop a system which incorporates the conclusions of the Preliminary Review into the Construction Permit processing.

Step 4. *Construction Inspections*

New Buildings

This step in the approval process consists of:

- inspections during construction,
- a final inspection upon the successful completion of construction, and
- in some communities, issuance of a Certificate of Occupancy upon approval of the final inspection.

These are officially carried out by authorities having jurisdiction, which may include not only the building department, but such other departments as fire, health, etc.

With the issuance of a construction permit (Step 3), the authority having jurisdiction usually establishes its inspection schedule. For construction inspections, this may be:

- inspections of specifically identified work items ("call-in" inspections by appointment);
- routine inspections independent of the progress of the work ("drop-in" inspections following the inspector's routine); or
- a combination of the above.

The purpose of construction inspections is to assure the conformance of the work to the approved plans and to specific code requirements. This may simply require the inspector to observe the work in progress. In some instances, measurements are necessary (e.g., spacing of structural members, pipe sizes, etc.), and sometimes tests are required (e.g., strength of concrete, plumbing DWV air and water tightness, etc.).

If any work is found not to comply with the approved plans or the code, it must be corrected to conform.

With an approved final inspection or when a Certificate of Occupancy is issued, the construction documents, permits and inspection reports are made a part of the community's official records.

Rehabilitation

The construction inspection process for rehabilitation projects is the same as that for new building construction. There are some aspects of rehabilitation, however, which require special consideration in this step.

In rehabilitation, unforeseen conditions within existing construction are likely to be encountered. Also, construction documents are likely to be less detailed about existing construction. Both of these aspects of rehabilitation may require more care and effort in construction inspections with regard to:

- determining the conformance of existing construction exposed during the work to applicable code requirements;
- establishing any increases in the scope of new work approved by the

construction permit(s) as a result of non-conforming existing construction;
- changing new work required by the condition of existing construction (e.g., obstruction of a new pipe chase by existing, concealed structural members); and
- carrying out an increased number of performance tests to establish final acceptance of the work (e.g., *Plumbing DWV Guideline for Residential Rehabilitation).*

These unique requirements of rehabilitation may be accommodated if a community implements the following:
- giving inspectors more authority to make decisions in the field,
- establishing procedures to support those field decisions, and
- improving the communication between plan reviewers and inspectors with regard to the scope, terms and conditions of new work approved on the construction permit(s).

Seattle, Washington, for example, has established and uses procedures which give inspectors more latitude to approve construction field changes in rehabilitation. Also, in major rehabilitation projects, Seattle plan reviewers visit the rehabilitation sites in order to expedite the start of projects.

Finally, the unique nature of rehabilitation suggests that special care be given to the recording of construction documents, permits and inspection reports in order to facilitate maintenance inspections and future rehabilitation.

Recommendation

- Institute the necessary practices, including training if required, to accommodate the unique inspection requirements of rehabilitation, such as increased inspector authority, improved communications, specific inspection techniques and performance testing.

Step 5. Maintenance Inspections

New Buildings

Once a building has a Certificate of Occupancy, it becomes subject to maintenance inspections throughout its life. These periodic, formal inspections sometimes may be made by a community's building department, but more often they are made by the fire and health departments or other authorities. These inspections are made to enforce property maintenance codes, fire prevention codes and hazard abatement codes.

If one of these inspections finds a building not to be in compliance with the applicable code, a correction notice may be issued and enforced by the courts. If such non-compliance is found to be an imminent hazard, and the condition is not corrected immediately, applicable enforcement procedures must be followed.

Rehabilitation

While the maintenance inspection of rehabilitated buildings is in almost every respect the same as that for new buildings, there may be special circumstances related to the conditions of approval of a rehabilitation project which require extra consideration in inspections, such as:
- posting of limited live loads (see *Guideline for Setting and Adopting Standards for Building Rehabilitation*),
- egress which generally is unacceptable for the elderly or handicapped (see *Egress Guidelines for Residential Rehabilitation*),
- egress which relies on alarms or sprinklers, or
- posting of a second electrical service entrance and disconnect (see *Electrical Guideline for Residential Rehabilitation*).

Recommendation

- Assure that any records used in the maintenance inspections of rehabilitated buildings adequately reflect all conditions of approval (established in Steps 2, 3 or 4 above) which may be subject to periodic inspection.

EGRESS GUIDELINE FOR RESIDENTIAL REHABILITATION

Table of Contents

I Prologue

Introduction

Egress requirements create a great number of technical problems and constraints in building rehabilitation. Existing exits which appear to be adequate will often not comply with the highly specific requirements for new building construction. Adding new exits or upgrading existing ones to meet new construction requirements can require the removal or alteration of otherwise sound structural elements such as walls, floors, hallway partitions, and doors.

The *Egress Guideline for Residential Rehabilitation* is not a code. It is to be used in conjunction with existing building codes, by persons knowledgeable in fire protection and building construction, to aid in interpreting the provisions of those codes for the special needs of rehabilitation. It is intended to facilitate the continued use of existing egress elements in the rehabilitation of buildings whenever feasible.

The guideline applies to one- and two-family dwellings and apartment houses less than 75 feet in height. Dormitories, lodging or boarding houses, and residential hotels that meet the conditions set out under *GENERAL ASSUMPTIONS* below could also be within the scope of this guideline. The goal of the guideline is to facilitate rehabilitation in circumstances where, for some reason, building code requirements for new construction are being applied. In general, there are two such circumstances:
- Repair and improvement of existing residential buildings, when compliance with the code requirements for new construction is triggered by a 25–50% Rule, or similar rule, which is in effect in the jurisdiction.
- Change of use or occupancy into a residential occupany (e.g., from one- and two-family dwelling to apartment house, from office building to apartment house, etc.), when compliance with the code requirements for new construction is triggered by the provisions of the building code in effect, or some other provision.

This guideline applies to "change of use or occupancy" rehabilitation when egress elements are already in place, or where other building elements (structural or non-structural) make literal code compliance impractical. By contrast, for example, this guideline does not apply to a warehouse that will be completely gutted during conversion to an apartment house. Such a conversion can, in most instances, be designed to meet new code requirements for egress without hardship.

This guideline is an endeavor to suggest solutions which will establish an approximately equivalent overall level

of fire safety without attempting to obtain literal code compliance. It is not a criticism of new construction requirements and does not imply that the suggested solutions are equivalent. Where compliance with new construction requirements does not present serious difficulty and is otherwise feasible, this guideline should not be the sole justification for non-compliance.

Communities that would not normally apply a new construction code to a rehabilitation project (e.g., the community has enacted its own building rehabilitation code) may still have use for selected portions of this guideline. There may be instances, though, where the solutions suggested below may be more stringent or restrictive than those already permitted or intended by the community. In such cases, the community must accept the responsibility to devise solutions that respond to unique local needs. The *Guideline for Setting and Adopting Standards for Building Rehabilitation* outlines a procedure to meet this task. Each community must assess its resources and its needs, and then define and set forth the codes, standards or regulations necessary to meet the common good.

Basic Fire Protection and Egress Principles

A safe means of escape from fire is fundamental to fire protection. But total evacuation of a building is not the only way to provide life safety from fire, and it is not always the most efficient: fire officials would need hours to totally evacuate a very tall building. Different building types will often pose different egress problems. Code requirements for egress must be responsive to the qualities and needs of the people to be protected and the hazards that they face.

The differing requirements of the three model building codes (Basic, Standard, Uniform) and the Life Safety Code illustrate that there is no single correct solution. The codes reflect the differences in opinion and philosophy that exist whenever professional judgment must be exercised. The issue is not which approach is most correct, but which is most appropriate once the character of the building and the occupants is known.

Given that a fire ignition has occurred, there are two basic approaches to solving the life safety problem:

- protect the people
- control the fire

The people could either be evacuated from the building or protected in place until the fire is extinguished and the danger passes. The fire can be controlled by suppression (e.g., automatic sprinklers) or compartmentation (e.g., fire resistive construction, protection of horizontal/vertical openings).

Smoke control systems attempt to prevent smoke and other fire gases from spreading throughout a burning building. Exits free of smoke can be used more safely and efficiently; the protection of occupants becomes more feasible because life-threatening combustion products are removed from the building. No specific recommendations have been included in this guideline concerning the use of smoke control systems, but the potential of the rapidly improving technology must be recognized.

In low and mid-rise residential buildings, the simplest and most direct solution is to evacuate the occupants. This may avoid the need to upgrade the fire resistance of major structural elements such as walls, floor/ceiling assemblies, and doors. Such major renovation is counter to the goal of decreasing the cost and complexity of building rehabilitation, particularly when alternatives are usually available.

The evacuation system consists of three interrelated component parts, and the guidelines build upon these relationships. The components are:

- fire detection and alarm;
- a path of escape or means of egress; and
- a safe destination.

In a one-and two-family dwelling "fire detection and alarm" is a smoke detector; the "means of egress" is the front door or escape window; the "safe destination" is the outside or some other protected area of refuge. The concepts are equally applicable to apartment houses, though the problems and requirements are more complex. Fire detection and alarm is more difficult because a single station smoke detector will only warn the occupants in a single unit, not the entire building. Two or more exists, instead of a single exit, are generally required.

The approach taken by the guideline is quite basic: identify the requirements, isolate the deficiencies, and then correct or compensate. To correct the deficiency is to comply with the code; to compensate for the deficiency is to meet its spirit and general intent. Note again the stated goal of this guideline: "an approximately equivalent *overall* level of fire safety."

There is no exact method for determining whether one set of corrective measures exactly equals another. But it is possible, with reason and professional judgment, to define the intent and purpose of code requirements, and then match these needs against the available fire protection techniques and materials. The task is made easier because, as noted above, while there are different approaches to solving life safety problems, these approaches are interrelated. Also, many fire protection measures have more than one impact.

For example, a suppression system can potentially control the fire, provide an emergency alarm to occupants, summon the fire department, and increase the time for safe escape by confining the fire to its compartment of origin and protecting the egress path. Improved lighting or additional handrails might compensate for deficient stairs when the number of occupants is small and the building occupants are physically able. Smoke detectors allow more time for escape while the fire is still in its incipient, least threatening stage and may permit early extinguishment.

The examples cited and the egress guidelines that have been developed are not exhaustive. There is no intent to limit the types of solutions that may be developed or considered effective. The guideline recognizes this, for the problems and solutions which have been included are headed "Selected Problems and Representative Solutions." Each building will present specific problems that will require specific treatment. Once the intent of the code requirement and the impact of the deficiency are understood, it may be possible to fashion an alternative solution. But the most important consideration will always be the character and status of the occupants and the use and arrangement of the building.

General Assumptions

Five assumptions have been made that impact upon the applicability of the Egress Guideline.

The rehabilitated structure must be intended for general residential use and the resident population representative of the population at large, which will likely include some elderly and handicapped persons. However, housing that is *primarily* directed towards elderly or handicapped persons is not within the scope of this guideline. The inability or increased difficulty of these persons to react quickly and properly, without assistance, to an alarm of danger requires an analysis and degree of safety that is beyond the generalized scope of this guideline.

It is assumed, that the occupants are familiar with their surroundings,

particularly the location of exits. This assumption makes the guideline inapplicable to hotels/motels or other occupancies with a transient resident population.

The population density is assumed to be small enough such that there would be no problem of queing at the exits. That is, all residents should be able to move continuously towards the exits without having to wait in line. This can be a problem in dormitories, boarding houses, and group residences. Therefore, the number and capacity of exits in these residential buildings must be given special attention.

Building codes contain a number of highly specific provisions controlling the quality of exits such as exit signage, illumination, emergency lighting, handrails, etc. It is assumed that both existing exits and any new exits that may be called for under this guideline will comply fully with these requirements.

Finally, it is assumed that the building is not deficient in too many areas. The concept of compensating for one deficiency by relying upon, or providing, other positive features becomes either too difficult or too tenuous if there are too many problems. For just as a single fire protection feature can provide several positive benefits, a single deficiency can have several negative impacts, and multiple deficiencies simply compound the problem further.

Arrangement of the Guideline

The various sections of the egress guideline have been placed in a sequence that parallels the procedure normally followed by local enforcing officials. They have been arranged as follows:

The occupant load (see discussion below), the physical characteristics of the building (e.g., height, area) and the use (e.g., apartment) determine the *minimum* number of exits that are required. Section 1 NUMBER OF EXITS addresses this area.

Once the required minimum number of exits is known, the number of available exits is counted. The concern is that the exits be of the proper type and that minimum fire resistive enclosure requirements, if any, are met. For example, some codes place limits on the use or number of horizontal exits. Generally, codes requires stairs to be enclosed by fire resistive construction. Guidelines have not been developed for every acceptable egress component, but Sections 2–5: HORIZONTAL EXITS; INTERIOR STAIRS/ENCLOSURES; EXTERIOR EXIT STAIRS; FIRE ESCAPE STAIRS apply here.

The location and layout of the qualifying exits is then examined. See Section 6: ARRANGEMENT OF EXITS. Improper arrangement may require that additonal exits be provided.

Access to these exits must also be evaluated and corrective measures must be taken as needed. Section 7: TRAVEL DISTANCE; Section 8: DEAD-END TRAVEL; and Section 9: CORRIDORS AND EXTERIOR EXIT BALCONIES should be applied at this time. As above, additional exits may be required if conditions are too severe.

Once the number of required exits has been provided and their arrangement and access is satisfactory, the capacity of the exits and minimum width dimensions must be considered. Section 10: EXIT CAPACITY/WIDTHS applies here.

Finally, the specific construction details of the egress components must be evaluated. See Section 11: CONSTRUCTION DETAILS AND SPECIFICATIONS.

There is a 3-part discussion within each of the eleven (11) Sections. First, there is a summary of code requirements and intent, including a discussion of the respective requirements in the Basic, Standard, and Uniform building codes. The Life Safety Code, published by the National Fire Protection Association, is not a building code, but has been included because it deals primarily with egress and has been used in a regulatory context.* Second, there is a discussion of how to identify conditions in the building to determine whether a problem exists. Third, there is a discussion of selected problems, some representative solutions, and a general narrative relating the two.

References to the applicable sections of the model codes have been included throughout the guideline. The references are as follows:

BOCA—Basic Building Code (1978 Edition)
NFPA—NFPA Life Safety Code (1976 Edition)
SBCC—Standard Building Code (1979 Edition)
UBC—Uniform Building Code (1979 Edition)

II Guideline

General Requirements

Smoke Detectors. Though smoke detectors can not control the growth or spread of fire, the early detection and alarm allows greater time for safe escape and possible control or extinguishment while the fire is still developing. This is particularly important in residential occupancies when all the occupants are asleep. Of course, the detector must be properly installed, located, and maintained.

Therefore, the installation of single station smoke detectors for each sleeping area of every dwelling unit is hereby required in this guideline before allowing any significant deviation from the requirements for new construction.

The model codes referenced in the guideline already require the installation of smoke detectors in every dwelling unit.[2] However, not all local communities have adopted one of the model codes, an earlier edition of a code without the smoke detector requirement may still be in effect, or a community may have deleted the smoke detector requirement.

The net effect of some of the solutions suggested below is to meet the new code requirements, so the requirement for smoke detectors noted above would not apply. Smoke detectors must still be installed if otherwise required by the code. But where the community has chosen not to adopt such a general provision, there is no basis for imposing an additional requirement for smoke detectors if a particular deficiency has been corrected to meet the code. The appropriate sections of the guideline have been noted accordingly.

Height and Area Limitations. Building codes usually limit the allowable height and area of a building as a function of its occupancy and type of construction.

In the case of a change of occupancy (into a residential occupancy), the compliance of a rehabilitated building with the height and area limits of the code for new construction is hereby required before applying the solutions. recommended in this guideline. Code permitted allowances for increased height and/or area may still be applied.

Occupant Load

The occupant load is the number of people that can be expected to be present in the building. The occupant load is used to calculate the number of required exits and the capacity or required width of these exits.

The occupant load may not be reduced below a minimum specified in the code, regardless of the number of people expected. However, if the actual occupant load will exceed the minimum

* There are literally thousands of different building codes being enforced throughout the United States. The model building codes were selected only because they are nationally known and have been adopted, either in whole or in part, by many communities.

[2] The Life Safety Codes does not require smoke detectors in dormitories and only "on each floor level" of lodging houses. (11-5.3.2.1)

specified in the code, the actual occupant loading is used.

Though each code specifies how the occupant load is to be calculated, the general method is to divide the total gross area by a minimum design density of 200 sq. ft. per person. The only exception is 300 sq. ft. per person in one- and two-family dwellings and 50 sq. ft. per person in dormitories under the Uniform Building Code. The occupant load for each floor is also computed though the method may vary somewhat. (BOCA: 606.0; UBC: 3301(d), Table 33–A; SBCC: 1105.1; NFPA: 5–3.1, 11–1.5).

Given the low population density of most residential use buildings, occupant loading will rarely present a problem. The minimum dimension requirements are more often the source of difficulty. As a general rule, providing the minimum of two (2) exits will be adequate. In residential rehabilitation, it is usually the arrangement and quality of the exits, not the number of building occupants, that will be controlling.

Technical Guideline

1. *Number of Exits*

Summary of Code Requirements and Intent

The codes specify the minimum number of exits that must be provided. The exits must be adequate for each floor as well as for the building as a whole. Other considerations such as travel distance, remoteness, or capacity of existing exits may require additional exits to be provided. These issues are discussed separately and, therefore, are not considered here.

Code Intent. Requirements for a minimum number of exits are established to increase the reliability of the means of egress system. The intent is that for any single fire ignition that prohibits travel to one exit, there will be an alternate exit that can be used. This does not address multiple fire ignitions, as may be likely with fires that are incendiary (intentionally set).

Having a minimum of two means of egress is one of the most fundamental principles of life safety from fire. The codes do allow certain residential configurations to have only a single exit, but every one of these special cases must also comply with the separate, general requirement for operable windows of specified minimum dimensions. These windows allows for escape, provide a source of fresh air if it is necessary to await rescue, and allow for rescue of building occupants by fire service personnel. Therefore, even these buildings could be considered to have two means of escape. All rehabilitated buildings should have escape windows whenever feasible.

Code Analysis

Basic Building Code—1978

Not less than two exitways serving every story, except in one-and two-family dwellings, with the following exceptions where one exitway is accepted (609.2, 609.3):

- on the first story of buildings 2,000 sq. ft. or less with an occupancy load less than 50 on the first story;
- residential multi-family buildings, two stories or less, with four or less dwelling units per floor, maximum exitway access travel of 50 ft., minimum one hour fire resistance rating of exitway enclosure, and minimum one hour opening protection.

The 1980 Supplement added to Section 609.2 the requirement that a minimum of three exits are needed if the occupant load is between 501 and 1,000 persons, and a minimum of four exits must be provided for occupant loads in excess of 1,000.

Uniform Building Code—1979

Every building or usable portion thereof must have at least one exit, except if there are over ten occupants, there must be two exits. Floors above the first story having an occupant load of more than ten shall have not less than two exits, subject to the following two exceptions:

- unless the number of occupants exceeds ten; only one exit shall be required from a second floor area within an individual dwelling unit;
- two or more dwelling units on the second floor may have access to only one common exit when the total occupant load does not exceed ten.

The latter requirement for two exits is applied to individual dwelling units as well: a single apartment unit larger than 2,000 sq. ft. (10 occupants × 200 sq. ft. per occupant) would require two exits from the private unit onto the public exitway; a similar requirement applies to an individual unit of a one- and two-family dwelling larger than 3,000 sq. ft. (10 occupants × 300 sq. ft. per occupant), even if it were a one story building.

Floors above the second story and basements, regardless of the occupant loading, require not less than two exits except when used exclusively for the service of the building; only one exit shall be required from a basement within an individual dwelling unit. As noted above, individual units and basements with an occupant load greater than ten must have two exits as well. Every story or portion thereof having an occupant load of 501 to 1000 shall have not less than three exits; four exits are required when the occupant loads exceeds 1000. (3302(a), Table 33–A, A–1215(b,d)).

Standard Building Code—1979

Not less than two independent exits except for one- and two-family dwellings and other exceptions noted below.

Minimum number of exits:	*Occupant load*
2	50 to 500.
3	501 to 1000.
4	More than 1000.

Residential occupancies having not more than four dwelling units per floor, less than 3500 sq. ft. per floor, and less than three stories in height may be served by one common exit. The travel distance from the entrance door of any living unit to the single exit cannot exceed 30 ft. (1103.2).

NFPA Life Safety Code—1976

Two separate exits are required with the following exceptions:

- one- and two-family dwellings;
- a unit with direct exit to the street at ground level, by an outside stairway, or by a one-hour rate enclosed stair serving only that apartment;
- any height building with four or less units per floor with direct access to a smoke proof tower or outside stair (20 ft. maximum travel distance);
- building three stories or less with one-hour exit and protected openings, corridors with one-hour rating, 20 ft. maximum travel distance (11–3.2.4).

Summary. A minimum of two exits is generally required, although some residential occupancies can have only one if certain requirements are met. The codes are not consistent as to when only one exit will be allowed.

Identifying Existing Conditions

Determine the required number of exits by considering (depending on the particular code in force):

- occupancy (one- and two-family vs. apartment house);
- area (for computation of occupant load);
- number of dwelling units;
- number of stories;
- arrangement of spaces (service rooms, two story dwelling units, etc.).

Determine the number of apparent exits for each floor in the proposed building, by counting the number of separate paths that discharge to a public way or protected area of refuge. The exits, or exit elements, either alone or in combination, are:

- interior stairway;
- exterior stairway;

- horizontal exit;
- smoke proof tower;
- fire escape;
- ramp;
- exit passageway;
- lobby or vestibule;
- exterior exit door.

The number of exits from any story is "apparent" because an element may be determined not to be an acceptable exit element because of violation of some other code provisions addressed later in the guideline.

Particularly in larger buildings, several required stairways and passageways may combine to discharge through a single exit passageway, lobby or vestibule. The codes impose limits upon exits that may combine at a later point, and care must be taken that this limit is not violated.

Selected Problems and Representative Solutions

1.1 *Problem:* Less exits are available than required.

Solution: Consider the use of means of escape, such as fire escapes (see Section 5 below), ladders, fire balconies, etc., which are not normally accepted by codes as exit elements for new construction, in order to provide the required number of exits. At least one exit should be a means of egress in substantial compliance with code requirements. This exit should preferably follow the path normally used by the building occupants. In an emergency situation, it is common for people to exit the same way they entered and to travel the path most familiar.[3]

Discussion: In accepting this solution, an analysis should be made which takes into account the public acceptability (e.g., would tenants share a common balcony or accept unlocked doors to create an area of refuge), the climate (e.g., accumulations of snow or ice), the ability of fire service personnel to effect rescue or gain access to the building to fight the fire, and the degree of mobility or agility necessary for safe escape.

1.2 *Problem:* One exit available in a building with three occupiable floors when two exits are required.

Solution: A single exit could be accepted if each floor arrangement meets the special conditions for a single exit for two story buildings (e.g., number of occupants or dwelling units, distance of exitway access travel), the stairway is well designed (dimensions as required by code, handrails, illumination, etc.), and the requirement for operable windows is met. The exitway must either be enclosed with construction having a minimum one (1) hour fire resistance or the apartments must be separated from the exit with construction having a similar rating. Existing wood lath and plaster in good condition may remain. Doors to the exit enclosure or apartment doors opening directly onto stairs must have a minimum one hour fire resistance. Existing doors, if substantial (e.g., minimum 1¾" bonded solid core door), may remain if provided with self-closing devices. Lesser doors must be protected on both sides by automatic sprinkler protection. These sprinklers may be connected to the domestic water supply and need not be equipped to sound a building alarm.

Discussion: A single exit is allowed by code for the specified arrangements up to two stories because the building is low, an escape window is required, the distance limitation on exit access, the requirement for compartmentation or exit enclosure, and the limited number of occupants. The requirement for smoke detectors and a high quality exit, coupled with escape windows, the limited number of occupants, and compartmentation, is the basis for extending the exception for a single exit to include buildings with three occupiable floors.

1.3 *Problem:* One exit available in a building over three stories.

Solution: A code complying smokeproof tower or exterior stair could be accepted as the single exit. The building must comply with the height and area requirements for new construction. The arrangement of each floor must meet the special conditions for a single exit for two story buildings and the stairway must be well designed and protected against the elements. Access to the exterior stair or smokeproof tower must either be open to the outside or by a protected corridor. Doors opening onto an enclosed corridor must be substantial (e.g., minimum 1¾" bonded solid core door) and provided with self-closing devices. Lesser doors must be protected on both sides by automatic sprinkler protection. These sprinklers may be connected to the domestic water supply and need not be equipped to sound a building alarm. Doors to a smokeproof tower must comply with the code.

Discussion: The Life Safety Code accepts a smokeproof tower or exterior stair as the sole exit for any height building with four or less units per floor with direct access to the exit (20 ft. maximum travel distance). It is also the traditional design method in Europe and much of the world. The added requirements for smoke detectors, compliance with height and area requirements, and an open air exit access or protected corridor increases the reliability of the single exit. The ability of the fire service to effect rescue or gain access to the building to fight the fire must also be considered.

2. Horizontal Exits

Summary of Code Requirements and Intent

Code Intent. The code intent is to provide an area of refuge within a building by providing a continuous barrier that will resist the passage of heat, smoke, and other fire gases. A horizontal exit is a passage from one building area to another. The areas must be separated by fire resistant construction with the appropriate opening protection (self-closing or automatic closing fire doors).

A horizontal exit does not have to be limited to one building, and can be a bridge or protected passageway from one building to another.

Code Analysis and Summary. A horizontal exit is a way of passage from a building to a protected area of refuge, on approximately the same level, within the same or another building. The area of refuge must afford safety from fire and smoke.

Walls or partitions forming the separation through which the horizontal exits provide passage must provide two hours fire resistance. Opening protection (e.g., fire doors, fire dampers) must have 1½ hours fire resistance. Fire doors in horizontal exits must be either self-closing or automatically close upon activation of an associated smoke detector, except that only automatic doors are allowed under the Uniform Code.[4] Doors must swing in the direction of exit travel, except that the occupant load must be fifty (50) or more under the Uniform and Standard Codes before this requirement is imposed.

The Standard and Life Safety Codes provide that horizontal exits cannot comprise more than one-half the required exits. The Uniform, Standard and Life Safety Codes require that the area of refuge into which the horizontal exit leads have an enclosed stair, door or other "standard" exit that leads directly to the exterior. The Basic Code requires one interior stairway or smokeproof enclosure on each side of the horizontal exit in multi-story buildings.

The area of refuge must be of sufficient area to be occupied by the

[3] This does not mean that elevators should be accepted as a means of escape. In such a case, it is the exit that most closely follows the normal path of entrance.

[4] A current change to the Basic Code only accepts automatic closing doors.

total occupant load of the connected areas based upon three sq. ft. per person (net). The codes contain various other prescriptive requirements relating to dimensions, materials and hardware. (BOCA: 614.0, and reported code amendment; UBC: 3307, 3303(b); SBCC: 1119; NFPA: 5-2.4)

Identifying Existing Conditions

Determine the fire resistance of the wall or partition assembly and protection of openings by reference to the code in effect, current or past listings, labels, or the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

Selected Problems and Representative Solutions

2.1 *Problem:* The fire resistance of the wall or partition, as determined above, is below that required by code.

Solution: Upgrade the wall or partition construction to meet code requirements.

Discussion: The fire resistance of the wall or partition should be improved by repairing the existing construction or adding a new layer(s) of fire resistive materials. See the *Guideline on Fire Ratings of Archaic Materials and Assemblies.* If the fire resistance is upgraded to code requirements, single station smoke detectors need not be installed, unless otherwise locally required.

Solution: Accept a wall or partition of one hour fire resistance. Doors must provide one hour fire resistance and close automatically upon activation of a smoke detector. The wall or partition should be carefully inspected to insure all penetrations, particularly ducts or other utility services, are properly protected and the existing materials are intact and structurally sound.[5]

Discussion: The single station smoke detector will provide added time for escape. Also, the expected severity of fires in residential occupancies should be contained by one hour fire resistive construction.

2.2 *Problem:* Fire resistance of the opening protection, as determined above, is below that required by code.

Solution: One hour doors may be accepted if protected on both sides by automatic sprinkler protection. These sprinklers may be connected to the domestic water supply and need not be equipped to sound a building alarm. Otherwise, the door must be upgraded to meet the code requirements or replaced.

[5]The area of refuge to which the horizontal exit leads must have either a complying exit stair or exterior exit door.

Discussion: The water spray from the local sprinkler will compensate for the reduced fire resistance.

2.3 *Problem:* The only exit from an area of refuge is another horizontal exit, in violation of the code.

Solution: Accept such an arrangement (i.e., *one* intermediate compartment) if the fire resistance of all walls or partitions separating the compartments, and the protection of all openings in the walls or partitions, fully comply with the code requirements.

The area of refuge reached after passing through the intermediate compartment must have a complying stair or exterior exit door.

3. Interior Stairs/Enclosures

Summary of Code Requirements and Intent

Enclosed stairs are recognized as an exit by all codes if they are properly designed and constructed. In multi-story buildings they are the most likely type of exit to be encountered. They provide a protected means for evacuation of a building by its occupants. By their nature as vertical shaft through a building, stairs also provide a potential path for the spread of fire from floor to floor.

Code Intent. Requirements for a fire resistive enclosure of stairs are established in order to achieve the following objectives:

- to provide a protected way from any story of a building to a public way or to an area of refuge;
- to limit the spread of fire from floor to floor;
- to provide a protected access for fire service personnel.

Code Analysis

Basic Building Code—1978

Required interior exitway stairs must have an enclosure of 1-hour fire resistance rating in buildings three stories or less, 2-hour fire resistance rating in buildings four stories or more. Stairs within a single dwelling unit are excepted. Also excepted, when automatic sprinkler protection is provided, are stairs between no more than three communicating floors close to street level which serve no more than one-half the required occupant load and which have adequate capacity for all occupants of all the communicating levels.

Stairway doors must be self-closing and have a 1-hour fire resistance rating in 1-hour construction and 1½ hour rating in 2-hour construction. Labeled fire doors shall have a maximum transmitted temperature end point of not more than 450°F above ambient at the end of 30 minutes of standard fire test exposure. Other openings are limited in area and must be protected. (616.6.3, 616.9.2, Table 214)

Uniform Building Code—1979

For new construction, interior stairways are required to be enclosed, with the following exception: stairways in one- and two-family dwellings, and stairs within individual apartments need not be enclosed. Enclosure walls must be a minimum of two-hour fire resistive construction in buildings more than four stories in height and not less than one-hour fire resistive construction elsewhere. All exit doors in an exit enclosure must be protected by a fire assemble having a fire resistance of not less than one hour where one-hour shaft construction is permitted and one and one-half hours where two-hour shaft construction is required. Doors must be maintained self-closing or automatic closing by actuation of a smoke detector. The maximum transmitted temperature end point shall not exceed 450°F above ambient at the end of 30 minutes of fire exposure. (3308(a)-(c), 4306(b))

Appendix Chapter 12 is a retroactive provision that establishes minimum requirements for all existing apartment buildings and hotels more than two stories in height. Because all such buildings would be required to comply with these minimim safety regulations, Section 103 of the Uniform Code provides that a community must specifically adopt the Appendix for its provisions to apply.

Appendix Chapter 12 sets forth the following requirements. Every interior stairway must be enclosed with walls of at least 1-hour fire resistive construction. Wood lath and plaster in good condition is acceptable as 1-hour construction for this purpose. The stairway need not be enclosed in a continuous shaft, but the continuity of the enclosure on each floor is required. Enclosurers are not required if an automatic sprinkler system is provided in all portions of the building except apartments. Stairway doors must be self-closing and equivalent to a solid wood door not less than 1¾ inches thick. (A-1215(f))

Standard Building Code—1979

Required exit stairs must be enclosed in 1-hour fire resistive construction in buildings three or less stories in height; 2-hour fire resistive construction in buildings four or more stories in height. Exceptions are similar to those noted above for the Basic Building Code. (1106)

Stair doors must be 1½ hour fire resistive assemblies for 2-hour walls, and 1-hour fire resistive assemblies for 1-hour walls. The maximum transmitted temperature end point shall not exceed 450°F above ambient after 30 minutes of standard fire test exposure.

NFPA Life Safety Code—1976

Stairways must be protected as follows:

Fire resistance of walls in buildings of one-three stories shall be 1-hour; four or more stories, 2-hours. Fire resistance of doors in buildings of one-three stories shall be ¾ hour; four or more stories shall be 1-½ hours. In buildings provided with total automatic sprinkler protection, the fire resistance of walls in buildings of one-three stories may be reduced to ¾ hours; four or more stories, 1-hour. The fire resistance of doors in sprinklered buildings of any height shall be ¾ hour. (11–3.5.3.1.1, 11–3.8.3.1.1)

Exceptions, including the exception allowing unenclosed stairs as part of communicating floors, are similar to those noted above for the Basic Building Code. (6–1)

Summary. The Basic, Standard, and NFPA Life Safety Code generally have identical provisions (2-hours with 1-½ hour door over three stories; 1-hour enclosure and door below four stories), except that NFPA requires only a ¾ hour door in a 1-hour stair enclosure. The Uniform Code differs in that buildings up to four, rather than three, stories only need a 1-hour enclosure. The Uniform Code Appendix Chapter 12 contains much more lenient requirements for existing residential buildings.

Identifying Existing Conditions

- Determine location of all unenclosed stairs.
- Determine the fire resistance of stair enclosures and doors by reference to the code in effect, current listings, or the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

Selected Problems and Representative Solutions

3.1 *Problem:* The fire resistance of the stair enclosure, as determined above, is below that required by the code in effect.

Solution: The fire resistance of the stair enclosure should be improved by repairing the existing construction or adding a new layer(s) of fire resistant materials. See the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

Discussion: If the fire resistance is upgraded to code requirement, single station smoke detectors need not be installed, unless otherwise locally required.

3.2 *Problem:* A 2-hour enclosure is required and an unenclosed stair does not meet the applicable code exception for communicating floors.

Solution: The stair may be enclosed at each story by construction having 1-hour fire resistance. The walls forming this enclosure may be located on each story wherever convenient, but as close as possible to the stair. Walls should extend through any concealed or void spaces to the underside of the floor above. Any area or section of a floor/ceiling assembly necessary to form a continuous enclosure from story to story must also have 1-hour fire resistance rating.

If necessary, a limited number of apartment doors may open directly onto the stair enclosure. These doors must provide one hour fire resistance, be selfclosing, and meet all other code requirements for stairway doors.

Discussion: The proposed solution provides a protected way of escape from any story while limiting the potential of fire spreading from floor to floor. The population density is low and the fire loading is not excessive. Single station smoke detectors will allow more time for escape.

3.3 *Problem:* A 1-hour enclosure is required, and an unenclosed stair does not meet the applicable code exceptions for communicating floors.

Solution: The stair may be enclosed at each story by construction having a fire resistance of 45 minutes (e.g., ½" type X gypsum wallboard). Up to 25% of the wall area on any given floor may be fire-rated wire glass in a steel frame. Substantial doors (e.g. minimum 1-¾" solid bonded core door) may be used if provided with self-closing devices.

Discussion: Reducing the required fire resistance from one hour to 45 minutes should still allow adequate time for safe escape given the smoke detectors and low occupant loading. The use of wired glass is often least objectionable from architectural and security considerations.

3.4 *Problem:* A 1-hour enclosure is required, and the stairway is enclosed with wood lath and plaster construction.

Solution: Accept the existing enclosure if it is in good condition and all penetrations and openings are either sealed or properly protected. A visual check should be made to insure the quality of the existing construction. There should be no other serious code deficiencies in the building.

Discussion: The presence of smoke detectors, the absence of any other serious code deficiencies, and the limited occupant loading make it reasonable to allow the existing enclosure to remain.

4. *Exterior Exit Stairs*

Summary of Code Requirements and Intent

Code Intent. The code intent for exterior stairs is the same as for interior stairs. However, because the stairs are outside the building, they do not create a vertical shaft through which the fire could spread. An important consideration, though, is the proximity of an exterior stair to openings in the exterior walls: a fire inside of the building could break out windows or other openings and cause the stair to become impassable.

A visual enclosure is sometimes required for exterior or outside stairs so that acrophobia (fear of heights) will not impede travel or lead to panic.

Code Analysis

Basic Building Code—1978

Exterior stairs may be used: (1) in buildings not exceeding five stories or 65 feet in height; and (2) where at least one door from each tenant opens onto a roofed-over open porch or balcony served by at least two stairways. Only one stairway is required if the code only requires a single exit. In buildings three or more stories in height, openings below and within 10 feet horizontally of the exterior stairs must be protected by automatic doors and windows of ¾ hour fire resistance. Exterior stairs must conform to the requirements for interior stairs in all other respects. (619.0)

Uniform Building Code—1979

For new construction, exterior stairs must meet the requirements for inside stairs except for opening protection. In buildings three or more stories in height, openings below or within 10 feet measured horizontally must be protected by a self-closing fire assembly having ¾ hour fire resistance except that openings may be unprotected when two separated exterior stairways serve an exterior exit balcony.

In existing buildings, (Appendix Chapter 12) the *only* requirements are that exterior stairs must be noncombustible or of wood of not less than 2-inch nominal thickness with solid treads and risers. (3305, 3305(1); Appendix Chapter 12, 1215(g)).

Standard Building Code—1979

Exterior stairs may be used: (1) in buildings not exceeding six stories or 75 feet in height; and (2) where at least one door from each tenant opens onto a roofed-over open porch or balcony

served by at least two stairways so located as to provide a choice of independent means of egress leading directly to grade. Openings below and within 10 feet horizontally of the exterior stair must be protected with ¾ hour fire resistive automatic opening protectives; opening protection is not required for buildings not more than three stories in height where all parts of the exterior stair are at least 6 feet from the building wall. Exterior stairs must conform to the requirements for interior stairs in all other respects. (1129)

NFPA Life Safety Code—1976

Where interior stairs are required to be enclosed, exterior stairs must be separated from the interior of the building by fire resistive walls as required for interior stair enclosures; fire doors or fixed wire glass windows must protect any openings therein. Such protection is not required in buildings three stories or less in height where there is a remote second exit. Other openings within specified distances must be protected. A "visual" enclosure must be provided for the benefit of persons afraid of heights. Exterior stairs must conform to the requirements of interior stairs in all other respects. (5–2.5)

Summary. The codes differ as to both when an exterior stair may be allowed and the need for protection of openings. The Basic and Standard Codes only permit exterior stairs in pairs. The Uniform Code does not require exterior stairs in pairs, but waives the requirement for opening protection if the second stair is provided. The Uniform Code, Appendix Chapter 12 for existing buildings, does not require protection of openings for a single exterior stair. Only the Life Safety Code requires a "visual" enclosure for the benefit of persons afraid of heights.

Identifying Existing Conditions

- Determine the fire resistance of walls or opening protectives within or adjacent to the exterior stairs by reference to labels, the code in effect, current listings, or the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

4.1 *Problem:* Fire resistance of the opening protection, as determined above, is below that required by the code in effect.

Solution: The openings need not be protected if there are a minimum of two exterior stairs located as to provide remote means of egress from an exterior exit balcony.

Discussion: This solution is recognized by the Uniform Code. It is unlikely that a fire would block the access to or the use of both exterior stairs. The requirement for single stations smoke detectors is added justification.

4.2 *Problem:* Fire resistance of the opening protection, as determined above, is below that required, and there is only a single exterior stair.

Solution: Upgrade the fire resistance of the opening protection by repairing the existing construction or adding a new layer(s) of the fire rated materials. See the *Guideline on Fire Ratings of Archaic Materials and Assemblies.* Windows must be wire glass in steel frames, either fixed or automatically closing, sealed, or otherwise made to comply with the code.

Discussion: If the fire resistance is upgraded to code requirements, single station smoke detectors need not be installed, unless otherwise locally required.

Solution: Install local sprinklers over opening protection. Such sprinklers may be connected to the domestic water supply and need not sound an alarm upon activation. Windows must be protected as above.

Discussion: The water spray on the exposed surface will compensate for the reduced fire resistance. The sprinklers should be located on the inside of the opening.

5. Fire Escape Stairs

Summary of Code Requirements and Intent

Code Intent. The code intent is to regulate the qualify of the required means of escape. Fire escapes are not favored because they are more difficult to traverse and afford less protection to occupants than other types of exists, such as enclosed interior stairs or exit passageways. However, properly designed and protected fire escapes can sometimes provide a practical solution when the existing number of exists or exit capacity is less than required.

Code Analysis

Basic Building Code—1978

Fire escapes are permitted only on existing buildings, and then only when "more adequate exitway facilities cannot be provided". Fire escapes cannot provide more than 50% of the required exit capacity. Doors and windows "along the fire escape" must be protected with 3/4 hour fire resistance rated opening protectives. (621.0).

Uniform Building Code—1979

Fire escapes are not allowed for new construction. Appendix Chapter 12 permits fire escapes to be used as one means of egress in existing buildings. Under specified conditions a "ladder device" may be used "in lieu of a fire escape". There are no requirements for protection of adjacent openings. (Appendix Chapter 12, 1215(h))

Standard Building Code—1979

If "more adequate exit facilities cannot be provided", fire escapes can be used on existing buildings four stories or less in height. Fire escapes cannot provide more than 50% of the required exit capacity. All openings within 10 feet of fire escapes must be protected with approved opening protectives of at least 3/4 hour fire resistance. (1116)

NFPA Life Safety Code—1976

Fire escape stairs may be used only in existing buildings, but shall not constitute more than 50% of the required exit capacity. Openings within specified limits "shall be completely protected by approved fire doors or metal-frame wire glass windows". (5–2.9)

Summary. Fire escapes are not accepted as a means of egress for new construction. The Basic, Standard, and Life Safety Code permit fire escapes in existing buildings, but only up to 50% of the required exit capacity. Appendix Chapter 12 of the Uniform Code, when adopted, allows a fire escape as "one means of egress" in "existing nonconforming . . . (apartments) more than two stories in height". All codes except Appendix Chapter 12 require adjacent openings to be protected, though the provisions are not consistent and there are exceptions. The codes all contain other higherly specific construction specifications.

Identifying Existing Conditions

- Determine that soundness and structural serviceability is as required by code.
- Determine that access to fire escape(s) is as required by code.
- Determine the fire resistance of the protection of openings by reference to labels, the code in effect, current listings, or the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

Selected Problems of and Representative Solutions

5.1 *Problem:* Fire resistance of the opening protection, as determined above, is below that required.

Solution: Upgrade the fire resistance of the opening protection by repairing the existing construction or adding a new layer(s) of the fire rated materials. See the *Guideline on Fire Ratings of Archaic Materials and Assemblies.* Windows must be wire glass in steel

frames, sealed, or otherwise made to comply with the code.

Solution: Install local sprinklers over opening protection. Such sprinklers may be connected to the domestic water supply and need not sound an alarm upon activation. Windows must be protected as above.

Discussion: The water spray on the exposed surface will compensate for the reduced fire resistance rating. The sprinklers should be located on the inside of the opening.

6. Arrangement of Exits

Summary of Code Requirements and Intent

Code Intent. The intent of providing exit remoteness, when two or more exits are required, is to minimize the probability that access to the exits will be blocked by any one fire. The term "remote" is subjective and frequently a matter of interpretation.

Exits which appear to be remote from each other sometimes converge at a distant point. Stairways discharging into a common lobby or passageway are examples. These exits are not truly remote because a blockage at the point of confluence renders both exits useless.

Code Analysis and Summary. Exits must be located so that they are discernible and have unobstructed access. They also must be arranged to lead directly to the street. When more than one exit is requiired, exits muist be as remote from each other as practicable, and must be arranged to allow direct access in separate directions. Exits shall be arranged and constructed as to minimize any possibility that both may be blocked by any one fire or other emergency condition. (BOCA: 602.2, 602.3; SBCC: 1103.1; NFPA: 5-5)

The Uniform Building Code has a prescriptive technique for determining exit remoteness. If two exits are required, they shall be placed a distance apart equal to not less than one half the length of the maximum overall diagonal dimension of the building or area to be served measured in a straight line between exits. An exception is made for exit enclosures interconnected by an approved corridor. Where three or more exits are required, they must be arranged a reasonable distance apart so that if one becomes blocked the others will be available. (UBC: 3302(c))

Identifying Existing Conditions

The arrangement of the acceptable exit components will be noted on the building plans or may be studied by a visual inspection of the physical structure.

ACCEPTABLE

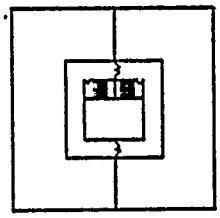


FIGURE 1

The smoke partitions could be constructed of wire glass, gypsum or other suitable materials. Construction similar to the existing corridor walls is also acceptable. The barriers must extend from exterior wall to exterior wall and from the floor to the underside of the floor or roof above, through any concealed or void spaces. Existing walls and partitions can be used to help form this continuous barrier.

The doors need not swing in the direction of exit travel, but double-acting doors are not acceptable. Doors shall close automatically upon the activation of an associated smoke detector. Doors, when closed, must fit tightly and prevent the passage of smoke. Minimum corridor or hallway dimensions should be observed as closely as possible. See Section 7: TRAVEL DISTANCE, if travel distance limitations are exceeded.

Solution: Provide additional exit(s) (e.g., stair, fire escape, fire balcony).

Selected Problems and Representative Solutions

6.1 *Problem:* Required exits not remote from one another.

Solution: Separate the non-remote exits by smoke barriers located as to establish distinct and separate smoke zones.

Discussion: With certain building configurations it is possible to isolate non-remote exists from one another. By constructing smoke barrier partitions, the requirement of direct access to the exits in separate directions can be met. Figure 1 illustrates this concept. No matter where the fire may originate, any occupant can safely pass from one zone into another. This approach would not work for the building in Figure 2 because these exists, though now in separate zones, cannot be reached by moving in separate directions: a fire blocking one exit would block the second.

NOT ACCEPTABLE

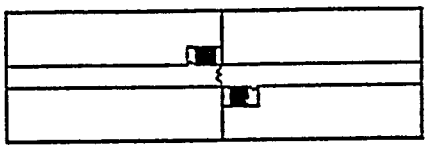


FIGURE 2

Discussion: If separation of the exits as discussed above is not possible, then additional exits must be provided so that all occupants will have remote access to the required number of exits. The quality of the additional exits (e.g., enclosed stair v. ladder) will depend upon the use and occupancy of the building. If a high quality remote exit is provided (e.g., enclosed stair), single station smoke detectors need not be provided, unless otherwise locally required.

7. Travel Distance

Summary of Code Requirements and Intent

The codes specify maximum travel distance to the nearest exit.

Code Intent. The intent of requirements governing the maximum travel distance to an exit is to limit the time an occupant needs to reach an exit. When combined with the requirements for a minimum number of exits and for exit remoteness, the limitation on travel distance is intended to assure that even if one exit is blocked by the fire, any occupant will still be able to reach a location of refuge before the fire has spread in a manner as to prevent it. The actual time for escape implied by the maximum travel distance limitation is not explicitly stated.

Code Analysis

Basic Building Code—1978

Length of "exitway access travel" to "an approved exitway" (defined as "that portion of a means of egress which is separated from all other spaces of a building by construction or equipment as required in this code to provide a protected way of travel to the exitway discharge") is as follows:

Without Fire Suppression System..... 100 feet
With Fire Suppression System..... 150 feet

If the travel distance within a living unit is less than 50 feet, or 100 feet if sprinklered, the distance of travel is measured from the "exitway access entrance to the nearest exitway" (i.e., from the apartment door). (607.4)

Uniform Building Code—1979

Maximum distance of travel "from any point to an exterior exit door, horizontal exit, exit passageway or an enclosed stairway" is as follows:

Without Automatic Sprinklers..... 150 feet
With Automatic Sprinklers..... 200 feet

These distances may be increased 100 feet when the last 150 feet is within a corridor that meet specific requirements as to width, height, obstructions, dead ends and openings. (3302(d))

Standard Building Code—1979

Maximum travel distance from any point to the "Nearest exit" (defined as "that portion of a means of egress which is separated from the area of the building from which escape is to be made, by walls, floors, doors or other means which provide the protected path . . . to the exterior") is as follows:

Unsprinklered..... 150 feet
Sprinklered..... 200 feet

If the travel distance within a living unit is less than 50 feet, the distance of travel to an exit is measured from the corridor entrance. (1103.1)

NFPA Life Safety Code—1976

The following are the requirements for travel distance (11–3.5, 11–3.6, 11–3.7, 11–3.8):

	To the nearest exit from an apartment entrance door (feet)	To a corridor door from any room door (feet)
No sprinklers or detection	100	50
Automatic dectectors	150	75
Partial sprinkler protection	150	50
Total sprinkler protection	150	100

"Exit" is defined similarly to "exitway" in the Basic Code.

Summary. The codes have varying dimensional requirements for travel distance. All allow an increase in exit travel distance if there are automatic sprinklers. Only the Life Safety Code allows an increase with automatic detection. The Uniform Code differs from the other codes by specifying the four egress elements to which the travel distance is to be measured.

Identifying Existing Conditions

Determine the distance from the most remote point on every story of the building or from the most remote apartment entrance door (depending on the local code in effect) to the nearest acceptable exit element. Measure the distance along the most direct natural path of travel.

Selected Problems And Representative Solutions

7.1 *Problem:* Measured travel distance exceeds maximum travel distance specified in applicable code.

Six alternative solutions to this problem are suggested below. Some of these solutions may be combined to get an additional increase in the allowable travel distance. A table showing the suggested cumulative increases for the different combinations follows the individual solutions. The maximum cumulative increase should not exceed 125 feet.

Smoke Barrier

Solution: The allowable travel distance may be increased by up to 75 feet if the path is divided by a smoke barrier with smoke actuated automatic closing door. The separation of non-remote exits (Section C: ARRANGEMENT OF EXITS) is a special application of this approach.

The smoke barrier could be constructed of wire glass, gypsum or other suitable materials. The barrier must extend from exterior wall to exterior wall and from the floor to the underside of the floor or roof above, through any concealed or void spaces. The doors need not swing in the direction of exit travel, but double-acting doors are not acceptable. Doors, when closed, must fit tightly and prevent the passage of smoke. Minimum corridor or hallway dimensions should be observed as closely as possible.

Discussion: The added compartmentation offered by the smoke barrier reduces the chance that the entire travel path would be blocked by smoke after a given period of time, thereby compensating for the added escape time due to a longer travel distance. The single station smoke detectors will also provide added time for escape.

Automatic Alarm/Heat Detector

Solution: The allowable travel distance may be increased by up to 50 feet if the building is equipped with an automatic fire alarm system activated by heat detectors located inside every apartment within 6 feet of the corridor door. The alarm should notify all building occupants. Entrance doors to apartments should be equipped with door closers.

Discussion: While the single station smoke detector will notify the occupants of an apartment, other building residents would not be made aware of the emergency. Interconnection of the individual smoke detectors, which are still required, is not realistic because of the large number of false alarms that may be expected. Heat detectors are less sensitive to the environmental causes of false alarms (e.g., burnt toast), but are still capable of providing an alarm before a fire could develop beyond the apartment of origin.

Manual Alarm

Solution: The allowable travel distance may be increased by up to 50 feet if a manual alarm system, not otherise required by code, capable of notifying all the building occupants, is installed. Entrance doors to apartments should be equipped with door closets.

Discussion: The smoke detector within the apartment will allow the occupant to escape while the fire is still small. The other building residents could then be warned by the sounding of the manual alarm.

Automatic Sprinkler/No Alarm

Solution: The allowable travel distance may be increased by up to 50 feet if an automatic sprinkler system is installed in the corridor and an additional sprinkler head is located to protect the apartment side of corridor doors. Such sprinklers need not sound an alarm upon activation. Doors must be provided with selfclosing devices. Single station smoke detectors are still required.

Discussion: The automatic sprinklers and door closers should contain a fire within the apartment of origin and keep the corridor passable.

Automatic Sprinkler/Automatic Alarm

Solution: If the partial sprinkler system discussed above is equipped to sound an alarm to all building occupants, the allowable travel distance may be increased by up to 100 feet. Door closers are still required.

Discussion: The sprinkler head inside each apartment door will perform a function similar to the heat detector in the automatic alarm solution by notifying other building occupants of a fire. The sprinkler system will help contain the fire within the apartment of origin and keep the corridor passable. Single station smoke detectors are still required to warn the occupants within the apartment of origin.

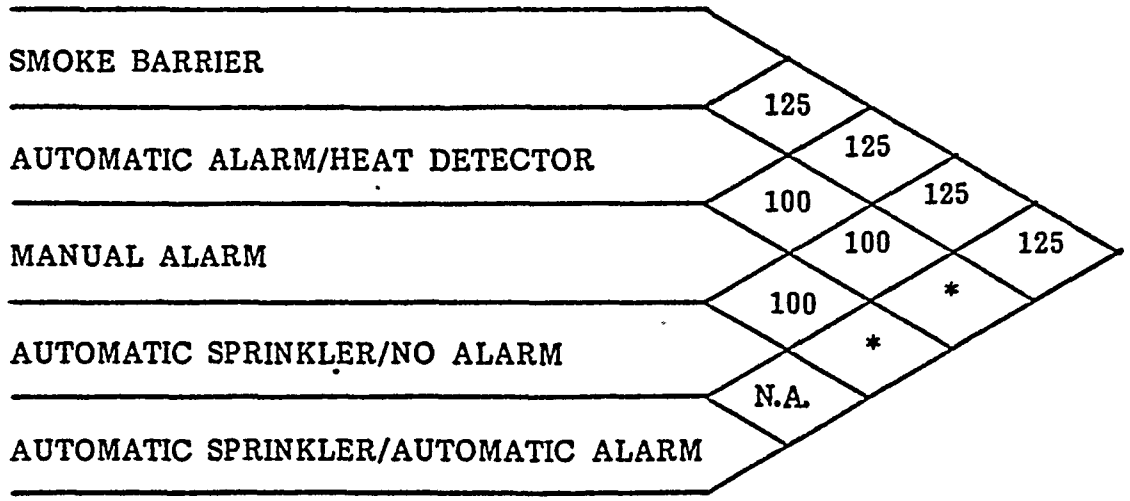
Provide Additional Exit(s)

Solution: Provide additional exit(s) (e.g., stair, fire escape, fire balcony) located so that travel distance limitations are not exceeded.

Discussion: The quality of the additional exits (e.g., enclosed stair v. escape ladder) will depend upon the use and occupancy of the building. If a high quality exits is provided (e.g., enclosed stair) single station smoke detectors need not be provided, unless otherwise locally required.

Suggested Cumulative Increases

The following chart contains the suggested cumulative increases if more than one solution is implemented.



The two combinations noted by an asterick (*) show no additional increase in travel distance because they perform similar life safety functions, e.g., the heat detector and sprinkler head inside the apartment door. However, there is an increase in reliability: there is a second system present should the first device fail to operate. There are also different fire scenarios where one system would be more responsive or appropriate than the other. The increase in travel distance is best left to the informed judgment of the local official, applied to the particulars of a specific structure.

8. *Dead-End Travel*

Summary of Code Requirements and Intent

Code Intent. Dead-end corridors of any length are undesirable features in buildings for two reasons. People who must use a dead-end corridor as part of the exit access (no choice of travel to exits) could be trapped by a fire or smoke between them and the exits. The other reason is that people moving within the exit access could enter the dead-end, especially under smoky or low light conditions, and become trapped or confused. Some controversy exists as to which concern the codes are intended to address, if not both. The answer is important because the design solutions differ.

All the codes use the term "dead-end" but do not define it. The Life Safety Code also uses the phrase "maximum single path corridor length", which would indicate a concern for the availability of two remote exits. The model codes appear to focus upon the individual who may turn off onto a dead-end corridor or hallway.

Code Analysis and Summary. The Basic, Uniform and Standard Building Codes impose a 20-foot maximum length for dead-ends (BOCA: 610.2; UBC: 3304(e); SBC: 1104.3). The Life Safety Code imposes a maximum single path corridor length of 30 feet, except that lengths of 35 feet are acceptable in existing or totally sprinklered buildings. (11–3.5, 11–3.6, 11–3.7, 11–3.8, as changed by the Tentative Interim Amendment)

Identifying Existing Conditions

There are two approaches to the identification of paths of dead-end travel. The result may not be the same in both instances.

From the perspective of an occupant in a corridor moving towards a proper exit(s), a dead-end is any path of travel onto which the occupant could mistakenly turn that does not lead to an exit. The length of the dead-end is the maximum distance that the occupant could travel before realizing the mistake, i.e., to the end of the dead-end path.

From the perspective of an occupant moving from an individual dwelling unit into the corridor, a dead-end is any path of travel for which no choice of exits exists, assuming that two or more exits are required. That is, an exit can be reached by traveling in one direction only. The length of the dead-end is the maximum distance that any occupant entering onto the corridor would have to travel until paths to remote exits become available. The dead-end corridor may extend beyond the most remote point of access from a dwelling unit to the corridor, e.g., to a window or janitor's closet. However, it is assumed that the occupants, familiar with their surroundings, would move toward, not away from the nearest exit. Therefore, for this perspective only, the length of the dead-end does not include the length of the path that does not lead to an exit. It would be included under the approach in the previous paragraph.

Representative Problems and Suggested Solutions

8.1 *Problem:* Excessive lengths of dead-end travel.

Solution: Provide an additional exit to eliminate the dead-end.

Discussion: The most direct solution is to construct an exit at or near the end of the dead-end path. A person turning off the main corridor would still have access to an exit; a person leaving an individual dwelling unit would have a choice of two remote exits. This exit must be directly accessible from the corridor or hallway. Higher quality exit components such as enclosed or exterior stairs are preferred. Fire escapes or balconies could be accepted depending upon the nature and characteristics of the occupant loading, fire department capabilities, building height, etc. If high quality exits are provided, single station smoke detectors need not be provided, unless otherwise locally required.

Solution: Construct a physical partition limiting the path of dead-end travel.

Discussion: By constructing a physical partition, a person who mistakenly turns off the proper path onto a dead-end would be alerted to his mistake. The distance from the proper path to the partition must be within the limits for dead-ends specified within the respective codes, but should be less than that allowed whenever practicable. The partition need not have any fire resistance rating. Any doors may be kept in the open position provided they shall close automatically upon the activation of a local smoke detector. The partition shall be clearly marked to indicate the path is NOT AN EXIT.

This solution does not provide two remote exits for those occupants whose dwelling units access onto the dead-end path. While the codes are not clear on this issue, the following analysis has been used. The portion of the building served by an excessive dead-end path is analyzed as though it were the second story of a two story building. Then, the number of exits required for this portion is determined. The conditions for allowing a single exit are noted in Section 1: NUMBER OF EXITS. If only one exit is required, then the building is considered to be in compliance because the dead-end path still provides one path of escape. The Uniform Building Code provides that "every building or USABLE PORTION THEREOF shall have at least one exit". (3302(a)) (emphasis added) Two exits are required only when certain limits are exceeded.

Travel distances for the dwelling units in this portion of the building are computed as follows:

The regular travel distance limitations outlined in Section 7: TRAVEL DISTANCE must still be met. For example, the travel distance from the door of the most remote dwelling unit in that portion of the building to the nearest exit may not exceed 100 feet in a non-sprinklered building constructed under the Basic Building Code.

Some codes impose a special limitation on travel distance to an exit when only one exit is required. The distance from the door of the most remote dwelling unit to the point where two remote exits become available must not exceed this limit. The Uniform Building Code has no such limitation. The allowable distances in the Basic and Standard Building Codes are 50 feet and 30 feet, respectively. Though the Life Safety Code allows dead-ends of 35 feet in existing buildings, the maximum travel distance when a single exit is allowable is only 20 feet.

Should the analysis reveal that the conditions for a single exit are not met by this portion of the building, then an additional exit must be provided.

9. *Corridors and Exterior Exit Balconies (Separation and Fire Resistance)*

Summary of Code Requirements and Intent

Corridors in Group R (Residential) occupancies are the common and public spaces through which occupants travel from their apartments to an exit element. It is the length of corridors that is usually controlled by code provisions governing travel distance.

The codes establish certain requirements for the separation of corridors from other building spaces. See also Section 10: EXIT CAPACITY/ WIDTHS for dimensional requirements for corridors.

Code Intent. Fire resistance requirements for corridor enclosures and doors are intended to maintain the integrity of the corridor and prevent flames and smoke from blocking the exit route. This will enable the occupants to safely travel through the corridors to the exits.

Code Analysis

Basic Building Code—1978

A corridor is defined as "a hallway, passageway or other compartmented space providing the occupants with access to the required exitway of the building or floor area". (201.2)

Corridors serving more than 30 occupants (i.e., floor area greater than 6,000 sq. ft.) must have a fire resistance rating of one hour. Corridor walls must extend from the floor to the ceiling (need not extend through space above suspended ceiling). Doors opening onto corridors serving over 30 occupants must be self-closing or automatic closing, with a 20-minute fire protection rating. (610.4)

Open porches or balconies leading to exterior exitway stairs must be separated on their interior side by a fire resistance rating of one hour in buildings of three stories or less, and of two hours in all other buildings. Doors in such separations must be rated ¾ hour and 1½ hours, respectively. Other openings must be protected and are limited in area. (619.1.1)

Uniform Building Code—1979

Corridor is not specifically defined.

Walls of corridors and interior sides of exterior exit balconies serving an occupant load of 30 or more (i.e., floor area 6,000 sq. ft. or more) must be of not less than one-hour fire resistive construction. Ceiling of corridors must be at least that required for a one-hour fire resistive floor/ceiling assembly.

Where corridor walls are required to be of one hour fire-resistive construction, doors must be "tight-fitting smoke and draft control" self-closing or automatic closing assemblies with a 20-minute fire protection rating. Other openings in corridor walls must be fixed and protected by ¼-inch wired glass in steel frames and may not exceed 25% of the wall area separating any room and the corridor. Protection of openings in the interior walls of exterior exit balconies is not required. (3304)

Travel distance in an enclosed corridor may be increased (see Section 7: TRAVEL DISTANCE).

Standard Building Code—1979

Corridor is not specifically defined.

All exit access corridors serving over 30 occupants (i.e., floor area greater than 6,000 sq. ft.) must have a minimum fire resistance rating of one hour. An exterior balcony may serve as a corridor (exit access) if it complies with all the requirements of a corridor. Doors opening onto corridors serving over 30 occupants must be self-closing, tight fitting, smoke and draft assemblies with a 20-minute fire protection rating. (702.3, Table 700 and Notes, 1108)

NFPA Life Safety Code—1976

Corridor is not specifically defined.

Walls enclosing exit access corridors must have a fire resistance of 1 hour. The fire resistance may be reduced to ¾ hour and ½ hour for buildings with automatic detectors and automatic sprinklers, respectively; ½-hour fire resistance is permitted in existing buildings.

Doors opening onto such corridors must have a 20-minute fire protection rating, except that previously approved 1¾ inch rated bonded wood core doors and frames may remain in use. Doors between apartments and corridors must be self-closing. (11–3.2.8, 11–3.5.3.1.3 and Exception No. 2, 11–3.6.3.1.3, 11–3.7.3.1.3, 11–3.8.3.1.2)

Summary. The Basic and Standard codes require a 1-hour enclosure and 20 minutes for doors for corridors serving over 30 occupants; the Uniform Code applies similar requirements when the occupant load is 30 or more. The Life Safety Code requires a similar corridor enclosure, irrespective of occupant loading, but allows reduction of the separation requirement as a function of automatic detection and extinguishment. Only the Life Safety Code accepts lower ratings for existing buildings. All codes require doors to have some form of door closing mechanism.

The three model codes disagree on the treatment of exterior exit balconies. The Uniform and Standard Codes treat them as corridors, while the Uniform Code does not require openings in interior walls of exterior exit balconies to be protected. The Basic Code seems to be stricter, treating them as parts of "exitways" rather than "exitway access".

Identifying Existing Conditions

Determine the occupant load served by the corridor in question. If it is in excess of the code specified criteria of 30 occupants (or 6,000 sq. ft. of area served), proceed with the following:

- Determine the fire resistance rating of the corridor wall assembly by reference to the code in effect, current listings or the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*
- Identify all other openings in corridor walls, such as transoms, and determine their area and the design of their closing devices, if any.
- Determine the presence and operability of door closing devices.

Selected Problems and Representative Solutions

9.1 *Problem:* The fire resistance of the corridor enclosure, as determined above, is below that required by the code in effect.

Solution: If the existing corridor wall consists of wood lath and plaster in good condition, it should be accepted as having adequate fire resistance. If of lesser construction or in need of repair, the fire resistance of the corridor enclosure should be improved by repairing the existing construction or adding a new layer(s) of fire rated materials. See the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

Discussion: If the fire resistance is upgraded to code requirements, single station smoke detectors need not be installed, unless otherwise locally required.

Solution: A corridor enclosure of 30 minutes fire resistance should be accepted. Buildings with more than three occupiable floors must be equipped with an automatic fire alarm system activated by heat detectors located inside every apartment door to the corridor. The alarm should notify all building occupants. Entrance doors to apartments should be equipped with door closers.

Discussion: The door closers, single station smoke detectors, and automatic fire alarm system (when required) will provide earlier detection and alarm and increase the reliability of the compartmentation. The corridor walls should be carefully inspected to insure that they extend from the floor to the underside of the floor above, are properly firestopped, and that any poke-throughs or penetrations are properly protected. There should not be any other serious code deficiencies.

9.2 *Problem:* The fire protection rating of corridor doors is lower than that required by the code in effect.

Solution: Unrated corridor doors should be accepted if they are individually equipped with a local sprinkler which will spray the door in case of a fire on the room side of the corridor door. Such a sprinkler may be connected to the domestic water supply system and need not sound an alarm upon activation. Doors should be provided with self-closing devices.

Discussion: The water spray on the exposed surface will compensate for the reduced fire resistance rating.

Solution: Upgrade the existing corridor doors. See the *Guideline on Fire Ratings of Archaic Materials and Assemblies.*

9.3 *Problem:* The corridor walls have openings other than doors which are inadequately protected as required by the code in effect.

Solution: All transoms should be closed with plasterboard, fixed wire glass, or other like materials. Other openings should be improved by repairing the existing construction or adding a new layer(s) of fire rated materials.

Discussion: See the *Guideline on Fire Ratings of Archaic Materials and Assemblies* for guidance. If the fire resistance is upgraded to code requirements, single station smoke detectors need not be installed, unless otherwise locally required.

Where the sealing of transoms or the use of wire glass would seriously compromise the character of a building, flexibility should be shown. Partial sprinkler systems or alternate materials such as polycarbonate could be considered. Single station smoke detectors would still be required unless the fire performance of these materials or systems is documented as meeting code requirements.

10. *Exit Capacity/Widths*

Summary of Code Requirements and Intent

The codes regulate the capacity of the means of egress by relating required widths of the various elements of the means of egress to the occupant load they serve, and by establishing minimum widths for each egress element.

Code Intent. It is the intent of the codes to provide an exit capacity large enough to move the total expected occupant load into the exits before the access to exits becomes untenable.

Safe exiting time is implied in the codes only, and cannot yet be validly calculated. It was, however, discussed when the values for exit capacity were established by the NFPA Life Safety Code committee. Doors and other level egress components were considered to have a rated capacity of 60 persons per minute per 22 inch unit of exit width, and stairs were rated at 45 persons per minute per unit of exit width. This is considered a standard 4:3 ratio for pedestrian movement. These values are based on studies by the National Bureau of Standards and the London Transport Board. (National Bureau of Standards, *Design and Construction of Building Exits, Pub. No. M151,* Washington, D.C., NBS, 1935; London Transport Board, *Second Report of the Operational Research Team on the Capacity of Footways Research Report No. 95,* London: London Transport Board, 1958). If stairs are sized to a capacity of 75 people per unit, a time of 100 seconds is implied (75 people/unit divided by 45 people/minute-unit). The results are the same for corridor travel.

The 22 inch unit of exit width, which is used in all but the Uniform Building Code, represents the median width of the human body at shoulder height. Its origin is said to be in experience gained by the military.

The UBC requirements actually imply an exit capacity of 100 people per 24 inches of exit width. Using the 22 inch exit unit system this results in about 92 people per exit unit.

Code Analysis

Basic Building Code—1978

Capacity is based on a unit of egress width of 22 inches with 12 inches or more considered as ½ unit in addition to one or more units (608.1), except that a 40-inch door is considered to have two units of egress width.

Exit capacity (number of occupants) per unit of egress width (608.2):

	Without fire suppression system	With fire suppression system
Stairways	75	113
Doors, ramps, corridors	100	150

Minimum width:
- Corridors, ramps—44 inches (36 inches in 1- and 2-family dwellings)
- Door—32 inches (28 inches in 1- and 2-family dwellings)
- Stairway—44 inches (36 inches for occupancy load 50 or less)
- Fire escape—22 inches
- Passageway—44 inches or ¾ of aggregate widths of all stairways and doorways leading thereto, whichever is greater

Uniform Building Code—1979

The total width of exits (in feet) cannot be less than the total occupant load served divided by 50, divided about equally among the separate exits. The total exit width for any story is based on the occupant load of that story, plus a percentage of the occupant load of other floors which exit through the story under consideration: 50 percent of the first adjacent story above (and below, if applicable), and 25 percent of the story immediately adjacent to the first adjacent story. (3302(b))

Minimum width:
- Corridors, exit balconies, and passageways—44 inches for occupant load of 10 or more (36 inches within dwelling units) (3304(b))
- Doors—32 inches
- Stairways and ramps—44 inches for occupant load over 50; 36 inches for load of 50 or less (30 inches for private stairway) (3305(b))
- Exit courts—44 inches or tributary occupant load
- Fire escape (existing building only)—29 inches—clear access opening; 18 inches—stairs (Appendix Chapter 12, 1215(h))

Standard Building Code–1979

Capacity is based on a unit of egress width of 22 inches with 12 inches or more considered as ½ unit in addition to one or more units (1105.2)

Exit capacity (number of persons) per unit of egress width (1105.3):

Stairs.....75
Level travel (doors, ramps, corridors).....100

The minimum width:
- Any means of egress—36 inches (1105.3(e))
- Exitway access, corridors, ramps—44 inches (36 inches in 1- and 2-family dwellings) (1105.3(g))
- Stair—44 inches (36 inches for 50 or less occupants (1115.6(c))
- Courts, passageways—36 inches or aggregate capacity of all tributary means of egress (1112(c)); 44 inches or ¾ of aggregate tributary stair and door width (1128.2)
- Door—32 inches (1117.1(b))
- Fire escape—22 inches—stairs (1116(d))

NFPA Live Safety Code—1976

Capacity is based on a unit of exit width of 22 inches with 12 inches or more considered as ½ unit in addition to one or more units (5–3.2)

Exit capacity (number of persons) per unit of exit width (11–1.6.1):
- Level egress, class A ramps, doors—100 People
- Stairways and other types of exits—75 People (See Table 5–2.9.4 for fire escapes)

Minimum width:
- Any exit access, Doors—28 inches (currently being changed to 32 inches)
- Stairs—44 inches for occupant load of 50 or more; 36 inches for occupant load of less than 50 (5-2.2.1.2)
- Fire Escapes—22 inches (18 inches for 20 or less occupants (5–2.9.4)
- Ramps—44 inches for Class A (5–2.6.1.2) 30 inches for Class B (5–2.6.1.2)
- Exit Passageway—Aggregate of tributary capacities (5–2.7.3)
- Street floor exit—Aggregate capacity of street floor and ¾ of exit units of stairs from other floors discharging through street floor (11–2.2.3.1)

Summary

Three of the codes use the 22-inch exit unit in computing required exit widths. The Uniform Code differs from the other three codes in the method used; however, the resulting widths are close. Only the Basic Code allows an increase in the capacity per unit of egress width if the building is sprinklered.

Minimum widths are generally similar for all the codes, except that the Life Safety Code, as currently revised, accepts a minimum corridor width of 32 inches. The other codes require 44 inches in apartment buildings.

Identifying Existing Conditions

- Determine the number of exit units or feet of exit (depending on the code in effect) for each exit element identified in Section 1: NUMBER OF EXITS above; for each access corridor or hallway leading from any apartment to an exit; and for each grade level egress. Base the computation on the number of occupants served by the element in question, in accordance with the code in effect. When communicating stairs or other openings are present, attention must be given to the potential need for the simultaneous evacuation of multiple floors.
- Determine the required width of each egress element, corridor or hallway.
- Determine or measure the actual width of each egress element, corridor or hallway, and grade level egress identified above, by field measurement or scaling dimensioned plans.

Selected Problems and Representative Solutions

10.1 *Problem:* The width of a particular existing element, or a new element constrained by structural or architectural features of the building, is less than the minimum width specified in the code in effect.

Solution: If the element is wide enough to provide the required exit capacity and is equal to or greater than some minimal dimension, though lower than that specified in the code, it should be accepted. This new minimum should be over 22 inches. Twenty-eight inches should be considered, as formerly specified for some elements by all four codes.

Discussion: In most cases, considerations of functionality (movement of furniture, etc.), appearance, marketability, and accessibility to the handicapped will result in minimum dimensions greater than those suggested above, and may in fact, have been the reason for the higher minimums specified in current codes. For egress only, however, one unit of exit width should be adequate given the lower occupant loading. A higher minimum than 22 inches is suggested, since that dimension represents a median width of the human body at shoulder height.

11. *Construction Details and Specifications*

Summary of Code Requirements and Intent

Code Intent. The codes set out many other requirements for egress components. Typical areas include: allowable materials, handrails, tread and riser design, landings, platforms, guards, door hardware, signage, lighting, alarms, and emergency lighting. The intent of these provisions is to ensure a quality design that will promote safe and easy passability. The individual code requirements have not been set out because they are too numerous and highly specific.

Identifying Existing Conditions

The relevant features should be noted on the building plans or may be studied by a visual inspection of the physical structure.

Selected Problems and Representative Solutions

Because these provisions tend to be highly specific and detailed, existing egress components will often not be in compliance. However, the impact or effect of the deficiency must be realistically appraised in light of the number of occupants that will rely upon the egress component in question and their ability to use the egress component as it presently exists. If the numbers are small and the people generally representative of the population at large, then minor deviations should be tolerated.

For additional guidance to understanding potential problems and solutions related to stairway design, refer to NBS Building Science Series 108, *"Safety on Stairs"*, November 1978, and Building Science Series 120, *"Guidelines for Stair Safety"*, May 1979, National Bureau of Standards, U.S. Department of Commerce.

Of the many potential problems, there are three that appear the most common and raise the greatest concern.

11.1 *Problem:* Existing winding and/or spiral stairs not permitted by the code in effect.

Solution: Allow their continued use if occupants are generally representative of the population at large (mobile, agile, and capable of rapid movement under emergency condition); upgrade stairs in all other respects, particularly handrails and lighting.

Discussion: Winding or spiral stairs are not favored because the uneven tread pattern and changes in direction can make passage difficult. The use of these stairs could be continued if the occupants can be expected to use them safely and the stairs complied in other respects (e.g., not excessively steep or narrow). Lighting should be improved if necessary; emergency lighting, handrails, etc. should be improved or provided.

11.2 *Problem:* Non-conforming tread and riser dimensions.

Solution: Accept stairs which are steeper than those permitted by the code in effect. Handrails should be provided on both sides, and stairs should be upgraded where necessary. See Section 10: EXIT CAPACITY/WIDTHS for stairs less than the required minimum.

Discussion: All codes contain minimum tread and maximum riser dimensions. Some codes use the mathematical formula that the sum of (2 x rise) + run must be between 24–25 inches. Such criteria may arbitrarily eliminate stairs which are otherwise quite passable. Rather than the absolute values of stair dimensions, it is the non-uniformity of tread or riser dimensions within a given flight of stairs which is a major cause of stairway accidents. Non-conforming stairs may be considered for acceptance if they are uniform, and the occupancy is such that those who may need the stairs in an emergency are familiar with the particular characteristics. As in 11.1 above, the stairs should be otherwise of high quality and passable. Lighting should be improved if necessary; emergency lighting, etc., should be improved or provided.

11.3 *Problem:* Ceiling heights for stairs, passageways, etc. are lower than minimum specified by the code in effect.

Solution: Allow the continued use if passable by the occupants, provided the ceiling height is no less than the minimum door height specified by the code in effect.

Discussion: Low ceiling heights make an exit not only physically difficult to traverse, but can create an impression of closeness or of a closed space that may create a sense of apprehension, particularly if the path is also narrow or somewhat lengthy. If the number of occupants is low so that crowding would not be expected and the distance is not excessive, discretion should be exercised. The familiarity of the occupants with this egress component should also be considered. Lighting, particularly emergency lighting, is very important. A regular pattern of markings showing the direction of the ultimate exit to the outside can also be reassuring. Other aspects of the egress component should be improved or provided if missing.

Electrical Guideline for Residential Rehabilitation

Introduction

This guideline addresses only those select problem areas most identified with rehabilitation projects. The guideline is not a code, but like an electrical code, it is intended for use by persons knowledgeable about electrical design and installations. In general, the guideline addreses three subjects:

- setting and adopting electrical rehabilitation standards at the state or local level;
- inspecting existing electrical installations; and
- problems and solutions for hazardous conditions, adequate load-carrying capacity, and additions, alterations and extensions to existing electrical installations.

With regard to problems and solutions, this guideline is intended to be used in all types of residential occupancies except hotels, rooming houses, dormitories and housing for the elderly. Its use is intended to facilitate rehabilitation by the maximal re-use of existing installations in circumstances where, for some reason, code requirements for new construction are being applied to a project undergoing rehabilitation. In general, there are two such circumstances:

- repair and improvement of existing residential buildings when compliance with the code requirements for new construction is triggered by a 25–50% Rule or similar rule which is in effect in the jurisdiction; or
- change of use or occupancy into a residential occupancy (e.g., from one- and two-family dwelling to apartment building, from hotel to apartment building, etc.) when compliance with the code requirements for new construction is triggered by the provisions of the code in effect or some other provision.

In the latter circumstance (change of use or occupancy), this guideline should be used when it is feasible to reuse some portion of an existing electrical installation.

It has been long recognized that electrical codes pose special problems for rehabilitation projects. Some communities have adopted special electrical codes to be used for rehabilitation. For example, the City of Detroit's electrical code for rehabilitation is shown in Appendix 1 to this guideline. Some of the model electrical codes give the code enforcement authority the responsibility for making interpretations of the rules, for granting exceptions to the rules, and for waiving specific requirements of the code. An example of this "flexible" approach is provided by the National Electric Code (NEC):

- "Section 90–2.(c) Special Permission. The authority having jurisdiction for enforcing this Code may grant exception for the installation of conductors and equipment, not under the exclusive control of the electric utilities and used to connect the electric utility supply system to the service entrance conductors of the premises served, provided such installations are outside a building or terminate immediately inside a building wall."
- "Section 90–4. Enforcement. This Code is intended to be suitable for mandatory application by governmental bodies exercising legal jurisdiction over electrical installations and for use by insurance inspectors. The authority having jurisdiction of enforcement of the Code will have the responsibility for making interpretations of the rules, for deciding upon the approval of equipment and materials, and for granting the special permission contemplated in a number of the rules."
- "Section 90–5. Formal Interpretations. To promote uniformity of interpretation and application of the provisions of this Code, the National Electrical Code Committee has established interpretation procedures."

1. Establishing Standards for Electrical Rehabilitation

A community that may wish to use this guideline may also have a need to set standards for rehabilitating electrical installations. A process for doing this is discussed in detail in the *Guideline for Setting and Adopting Standards for Building Rehabilitation.*

In addition to the information in this guideline that a community may use to establish suitable requirements and criteria for rehabilitation, there are a number of other sources of information which may be used as a basis for setting electrical rehabilitation standards. Current electrical codes, such as the NEC, are one such source of rehabilitation standards information. Although these codes principally regulate new construction, and therefore may not adequately address the problems of rehabilitating existing buildings, certain of the provisions of electrical codes for new construction may be applicable. For example, those provisions regulating grounding, feeders and service ratings can be adopted as electrial rehabilitation standards when a community wishes to maintain a level of performance in rehabilitated buildings which is the equivalent to that for new construction.

In addition, the "alternative materials and methods" provision of new construction codes provides a concept by which some solutions to problems of electrical rehabilitation can be developed that are different from those prescribed by the current code.

Property maintenance codes, fire prevention codes, and hazard abatement codes could be another basis for setting electrical rehabilitation standards. As the following excerpts from some of these codes illustrate, they do not contain precise enough information to be useful in setting specific standards. They are useful, however, as a general basis for establishing both minimum levels of performance and levels of performance less than that required by new construction codes.

The BOCA Basic Property Maintenance Code states in Section H–602.0, ELECTRICAL FACILITIES:

"H–602.1 Outlets required: Where there is electric service available to a structure, every habitable room of a dwelling unit, and every guest room, shall contain at least two (2) separate and remote outlets, one (1) of which may be a ceiling or wall-type electric light fixture. In a kitchen three (3) separate and remote wall-type electric convenience outlets or two (2) such convenience outlets and one (1) ceiling or wall-type electric light fixture shall be provided. Every public hall, water closet compartment, bathroom, laundry room or furnace room shall contain at least one (1) electric light fixture. In addition to the electric light fixture in every bathroom and laundry room, there shall be provided at least one (1) electric outlet."

"H–602.2 Installation: All electrical equipment, wiring, and appliances shall be installed and maintained in a safe manner in accordance with all applicable laws. All electrical equipment shall be of the approved type."

"H–602.3 Defective system: Where it is found, in the opinion of the building official, that the electrical system in a structure constitutes a hazard to the occupants or the structure by reason of inadequate service, improper fusing, insufficient outlets, improper wiring or installation, deterioration or damage, or for similar reasons, he shall require the defects to be corrected to eliminate the hazard."

Similarly, the BOCA Basic Fire Prevention Code states in Section F–105.0, ORDERS TO ELIMINATE DANGEROUS OR HAZARDOUS CONDITIONS, F–105.1 General:

"Whenever th fire official or his designated representative shall find in any structure or upon any premises dangerous or hazardous conditions or materials as follows, he shall order such dangerous conditions or materials to be removed or remedied in accordance with the provisions of this code: . . . 7. hazardous conditions arising from defective or improperly used or installed electrical wiring, equipment or appliances;"

Past electrical codes for new construction are an expecially important source of information for setting electrical rehabilitaton standards. The levels of safety required by past electrical codes are different from, and may be lower than, the current electrical codes. Past codes, however, are most useful in determining after an on-site inspection whether an existing building currently meets the code under which it was built.

Finally, laws and regulations affecting electrical installations which apply retroactively to exiting buildings are by definition mandatory standards for electrical rehabilitation.

2. Inspection

In the process of submitting proposed electrical rehabilitation work to an authority having jurisdiction, it will be necessary to inspect existing electrical

installations when the authority needs more information about the work to be done (see *Guideline for Approval of Building Rehabilitation).* Inspections are also an essential part of enforcing property maintenance, fire prevention and hazard abatement codes.

This part of the guideline contains a procedure for conducting inspections of existing electrical installations to determine their physical condition, functional condition and load-carrying capacity.

Even if electrical construction drawings and/or specifications of an existing building are available, they are not always be useful for determining the present physical and functional condition of the electrical installation; these conditions can only be determined from an on-site inspection. However, if it is determined that electrical construction drawings accurately and completely represent the present electrical installation in an existing building, they could be used in conjunction with the current electrical code to calculate the installation's load-carrying capacity.

It is recommended that inspections be made by qualified electrical personnel, as determined by each jurisdiction.

2.1 Physical Condition—Step 1

Determine the physical condition of the existing electrical installation including individual dwelling units and common areas of multi-family dwellings. Inspect the physical condition of the parts of the installation which are normally exposed to view.

Next turn off the power of individual dwelling units and common areas of multi-family dwellings, and remove the covers and open the doors of switchboards, panelboards, cabinets and boxes. Inspect the physical condition of the exposed, internal components and wiring, as well as the surrounding building construction.

If the condition of the conductor insulation can't be determined by inspection, perform an insulation resistance test. Similarly, if the condition of receptacles can't be determined by inspection, test them by inserting a standard type flexible cord attachment plug.

Detach fixed utilization equipment such as lighting fixtures, lampholders and appliances (built-in electrical space heaters for example) to inspect the physical condition of their exposed, internal components and wiring, as well as the surrounding building construction. However, in older buildings, detachment may contribute to, or actually cause, defects in equipment, appliances or wiring. Therefore, consider detaching fixed utilization equipment only when:

(1) Such wiring, equipment or appliance is part of a rehabilitation plan;

(2) Problems are evident from the first inspection of parts which are normally exposed to view; or

(3) Problems of function are evident from inspection or records, or are identified by owners or tenants.

2.2 Functional Condition—Step 2

If the physical condition of the installation seems safe, determine the functional condition with the power on in individual dwelling units and in common areas of multi-family dwellings. Inspecting an installation with the power on is essential to determining its condition.

When a building or dwelling unit is without power because it is unoccupied or an imminent hazard exists, determining functional condition may have to be delayed until after rehabilitation has begun, or an exploratory permit may have to be secured by the building owner from an authority having jurisdiction to turn the power on.

Remove the covers and open the doors on equipment to expose circuit breakers, switches, receptacles and other devices, and conductor splices and connections; then:

(1) Operate circuit breakers, switches, other operable devices and fixed utilization equipment;

(2) Observe the function of operable devices; and

(3) Observe the operation, and assess the operating temperatures of fixed utilization equipment.

Make inspections to determine the physical and functional conditions of existing electrical installations in accordance with the current code, such as NEC Section 110-3(a). Whenever possible, as an aid in assessing an installation's condition, secure information from owners, tenants or from records of jurisdictions having authority about past operating problems that cannot be found easily by inspection, such as the frequency of fuses blowing or short circuits.

2.3 Load-Carrying Capacity—Step 3

Determine the load carrying capacity of the existing electrical installation by calculation in accordance with the current code.

3. Problems and Solutions

3.1 Hazardous Conditions

Problem. The existing electrical installation has any one or combination of the following conditions which are contrary to the intent of properly maintenance, fire prevention and hazard abatement codes:

(1) Equipment or wiring is missing, broken, disconnected, loosely connected, unsupported, not securely fastened in place, corroded, burnt, cracked, split, has evidence of overheating, physical damage or misuse;

(2) Equipment is dirty or contains debris;

(3)Wiring is frayed;

(4) Labeled or listed equipment or wiring is not installed in accordance with any labeling or listing instructions;

(5) Circuit breaker, fuse, switch, receptacle, other device, fixed utilization equipment or wiring is not compatible with the phase, voltage, amperage or type characteristics of the electricity in use;

(6) circuit breaker, switch or other operable device has visible evidence of arcing or overheating;

(7) receptacle contact devices are not firmly in contact with the contact devices of a standard type flexible cord attachment plug when the plug is inserted in the receptacle;

(8) bathroom receptacle, garage receptacle or outdoor receptacle with direct grade level access is without ground fault circuit interruptor protection;

(9) neutral is not grounded at the main service entrance equipment location by a properly connected grounding electrode conductor;

(10) polarity is reversed in wiring connections to receptacle outlets;

(11) fixed utilization equipment, such as a lighting fixture, lampholder or appliance, operates intermittently;

(12) building construction adjacent to wiring, equipment or appliance is burnt;

(13) service, feeder or branch circuit conductors have evidence of intermittent operation, impaired operation or cannot otherwise be determined as acceptable when the installation is energized;

(14) flexible cord is used as a permanent wiring method;

(15) branch circuit, feeder, switchboard, panelboard or distribution board service rating is inadequate for the load calculated in accordance with the current code; or

(16) pull-chain switch or brass shell socket in a wet or damp location is within reach.

Solution. Have all such conditions corrected.

Discussion. These conditions are hazards of varying degrees. They are problems associated with defective or improperly used or improperly installed wiring, equipment or appliances. If any one or combination of these conditions is extensive, severe or occurs frequently

in an installation, an authority having jurisdiction may judge that an imminent hazard exists. In that case, the hazard must be corrected immediately or the installation disconnected.

If flexible cord is used as a permanent wiring method (condition 14), this may indicate the need for more receptacle outlets (see 3.8 of this Guideline).

3.2 Incompatible Conductors, Devices or Equipment

Problem. Circuit breaker, fuse, switch, receptacle, other device, fixed utilization equipment, raceway, connector, terminal, splicing device or other fitting is not compatible with the type of conductor used, or the electrical connection doesn't meet the current code, such as NEC Section 110–14.

Solution. Have all such connections of conductors to terminal parts, conductor splices, or conductors joined with splicing devices corrected to meet the current code, such as NEC Section 110–14(a) and 110–14(b); and have all incompatible conductors, devices or equipment corrected to meet the current code, such as NEC Section 110–14, by:

(1) Replacing existing conductors with new conductors which are compatible with the existing devices or equipment; or

(2) Replacing existing devices or equipment with new devices or equipment which are compatible with the existing conductors; or

(3) Installing an insulated conductor "pigtail" compatible with the existing device or equipment.

Discussion. Improper connections and splices, and incompatible conductors, devices and equipment can be hazardous. There are problems associated with defective or improperly installed wiring or equipment. These conditions, depending upon the number and severity of the problems, may be judged an imminent hazard by an authority having jurisdiction. If that is the case, the hazard must be corrected immediately or the installation disconnected.

3.3 Grounding of Fixed Appliance Branch Circuits

Problem. An existing fixed appliance branch circuit doesn't have an equipment grounding means which is required by the current code.

Solution. Permit ungrounded, non-conforming, existing fixed appliance branch circuits to remain, provided:

(1) Alternative grounding is provided for appliances by the connection of an equipment grounding conductor to a grounded, metallic, cold water pipe;

(2) Service equipment, service raceways, service grounded conductors, switchboards and panelboards are grounded in accordance with the current code, such as NEC Article 250, or alternative grounding is provided by the connection of an equipment grounding conductor to a grounded, metallic, cold water pipe;

(3) Branch circuit equipment grounding conductors are in accordance with the current code, such as NEC Article 250; and

(4) Ungrounded, non-conforming, existing, general purpose branch circuits conform to 3.4 of this guideline.

Discussion. This alternative method of grounding existing fixed appliance branch circuits is not the method usually required by code, but it will provide an equivalent level of safety. And, since this alternative method is relatively simple to install, it is an aid to rehabilitation. But, it's important to make sure in such installations that equipment grounding conductors are connected to *cold* water pipes which are *metal* and which are *grounded.*

3.4 Grounding of General Purpose Branch Circuits or Feeders

Problem. An existing general purpose branch circuit or feeder is without an equipment grounding means which is contrary to the current code.

Solution. Allow ungrounded, non-conforming, existing, general purpose branch circuits or feeders to remain, provided that:

(1) no circuit or feeder is overloaded when the load-carrying capacity is calculated as in 2.3 of this guideline;

(2) no general purpose branch circuit serves loads required by the current code to be served by small appliance branch circuits; and

(3) no receptacle outlet or fixture is located where it will be in reach of grounded surfaces.

Discussion. An existing general purpose branch circuit or feeder without an equipment ground which is inspected, found to be still in acceptable physical and functional condition, and is not overloaded, can be considered to have a history of operating safely. Therefore, its safe operation can be expected to continue, and it may be allowed to remain. It is important that such a circuit doesn't serve as an appliance branch circuit; that in calculating loads on it, both existing loads which won't be affected by rehabilitation, and new loads which are a result of rehabilitation be used; and that the receptacle outlets and fixtures on such a circuit are safely located out of reach of grounded surfaces.

3.5 Undersized Service

Problem. The size of the service is inadequate for the load as calculated according to the current code.

Solution. Recalculate the size of the service for the actual connected (installed) load and the loads for circuits calculated according to the current code, provided:

(1) The service disconnecting means has a rating not less than the actual connected load;

(2) Loads established for branch circuits and feeders are determined with the diversities and calculation methods defined in the current code; and

(3) All other aspects of the service meet the current code, such as NEC Tables 310–16 to 19 including the notes to those Tables, Article 210, Article 220, Article 240 and Article 230 except Section 230–79(c) for single-family dwellings and Section 230–79(d) for all other occupancies.

Discussion. In determining the actual connected load, include both existing loads which won't be affected by rehabilitation and new loads which are planned as a part of rehabilitation. The probability of the use of room air conditioners should also be considered. By using energy sources other than electricity, electrical loads can be reduced. Therefore, consider the use of other energy sources for cooking, heating and domestic hot water. Determining existing loads and new loads planned as a part of rehabilitation requires judgment. If there is any indication that loads will increase in the future, this should be taken into consideration. Using the actual installed load is a means of control otherwise unnecessary rehabilitation, while maintaining the standards of safety required by the current code.

3.6 Second Service Entrance and Disconnect

Problem. In one- and two-family dwellings, the existing service rating is to be increased by the addition of a second service entrance and a second service disconnect in order to meet the current code or this guideline, but space is limited or there are other, similar constraints.

Solution. Add the second service entrance and the second service disconnect at a location different from the existing service disconnect, provided:

(1) Both disconnects meet the current code, such as NEC Section 230–44 and 230–72(a) and (c);

(2) Permanent warning signs are erected at each location indicating separate service disconnects; and

(3) The combined rating of the separate service disconnects is not less than that required by the current code or recommended by other sections of this guideline for a single service disconnect.

Discussion. These recommendations are intended to eliminate the potential hazard of installing a single, new, service entrance in an inappropriate location, and are a means to control otherwise unnecessary rehabilitation. Any hazard associated with a "split" service is also eliminated by the suggested provisions of the recommendations, and the restriction of split service to residences of no more than two families. A split service installed as recommended is an alternative to the current code which may provide an equivalent level of safety.

3.7 Extending General Purpose Ungrounded Branch Circuits

Problem. An existing general purpose branch circuit that is to be extended conforms to the current code, but doesn't have an equipment grounding means.

Solution. Permit ungrounded, non-conforming, general purpose branch circuits to be extended to all locations except kitchens, baths, basements, garages and locations within reach of grounded surfaces.

Discussion. Kitchens, baths, basements, garages and locations within reach of grounded surfaces represent a particular hazard as compared to other locations. That hazard is reduced by equipment grounding means installed according to the current code or this guideline.

3.8 Number of Receptacle Outlets

Problem. The number of existing receptacle outlets is less than required by the current code.

Solution. Permit fewer receptable outlets than required by the current code.

Discussion. The number and location of receptacle outlets required for the safe and convenient use (as this bears on safety) of rooms and spaces varies and can best be determined by the judgment of communities and jurisdictions individually. Such factors as number of occupants, floor area, room configuration, and window and door locations all affect determining that number and location of receptacle outlets which meets the intent of the current code. Examples of such reductions in the number of required receptacle outlets are contained in the BOCA Basic Property Maintenance Code, Section H-602.0, ELECTRICAL FACILITIES which is quoted in 1 of this guideline, and in Appendix 1 to this guideline, Chapter 10, Official Electrical Code of the City of Detroit.

3.9 Access to Electric Equipment

Problem. The configuration of access space to, and working space around, electric equipment to permit ready and safe operation and maintenance of the equipment is different from that required by the current code, such as NEC Section 110-16.

Solution. Permit such existing space to remain when the intent of the current code can be met.

Discussion. Equipment accessibility and working space are essential to safety. If the existing space meets the requirements of the past code under which it was constructed, if additional equipment and/or new equipment of a higher service rating is not to be installed, and if the installation has a history of safe operation, maintenance and repair; these considerations may be a basis for permitting the existing space to remain unchanged.

Appendix 1—Detroit Electrical Code, Chapter 10

Chapter 10 of the code is added as follows:

1000-1. Minimum standards for existing dwelling units.

If inspection reveals that the wiring system of an existing dwelling type occupancy is inadequate, or if code certification as a habitable dwelling under this section is requested, the following minimum requirements shall be complied with:

(a) Entrances and Exits: Where two (2) or more entrances and/or exits exist, at least two (2) entrances and/or exits shall be illuminated by exterior lights. Lighting outlets shall be controlled by interior wall switches, located for convenient and readily accessible use.

(b) Living Room: Living room shall be provided with illumination. Lighting outlet shall be controlled by a wall switch, located for convenient and readily accessible use. One of the receptacle outlets controlled by a wall switch in lieu of ceiling lighting outlet is acceptable. Convenient duplex receptacle outlets shall be provided. Receptacle outlets shall be equally spaced around the room with at least one duplex receptacle outlet on each wall.

(c) Kitchen: Kitchen shall be provided with illumination. Lighting outlet shall be controlled by a wall switch located for convenient and readily accessible use.

A separate kitchen appliance circuit shall be provided, supplying a minimum of three (3) grounding type duplex receptacle outlets. Two (2) of these receptacles shall be readily accessible for convenient use of portable appliances. New appliance circuits shall be twenty ampere capacity.

(d) Bathroom: Bathrooms shall be illuminated. Lighting outlet shall be controlled by a wall switch. A receptacle outlet separate from the light fixtures, shall be provided and shall be located at least thirty (30) and not more than forty-eight (48) inches above the floor adjacent to the wash basin and not more than four (4) feet from the basin.

(e) All Other Habitable Rooms: Illumination for each habitable room shall be provided. Lighting outlet shall be controlled by a wall switch. Wall switches shall be located for convenient and readily accessible use. Convenience duplex receptacle outlets shall be provided with a minimum of two (2) receptacle outlets equally spaced around the room. An additional receptacle outlet controlled by a wall switch is acceptable in lieu of a lighting outlet.

(f) Basement: Basement shall be wired for a minimum of one lighting outlet in each 200 square feet or major fraction of area for use as general illumination. All enclosed areas that may be walked into, such as toilet rooms, fruit storage rooms, utility rooms, excavated areas under porches, etc., shall be provided with at least one lighting outlet (except coal bins).

Stairwell and laundry area lighting outlets shall not be counted as part of the required basement lighting outlets.

(g) Laundry Areas: Laundry areas shall be provided with illumination. Laundry circuit shall be an individual circuit. A wall-mounted grounding type duplex receptacle outlet shall be provided, located near the laundry equipment.

An existing drop cord receptacle outlet on a separate circuit shall be acceptable providing it is a grounding type receptacle outlet not more than five (5) feet six (6) inches above the floor.

(h) Space Heating System: Heating equipment requiring electrical energy for operation and/or control shall be provided with an individual circuit. A disconnect switch shall be provided on or adjacent to the heating equipment (exception: thermo-pile controlled furnaces).

(i) Stairwells: Stairwells shall be adequately illuminated. Lighting outlets shall be controlled by wall switches. Wall switches shall be located for convenient and readily accessible use. Switches shall not be located where it is necessary to use darkened stair sections for their operation. All stairwells to finished portions of dwelling shall be

provided with multiple switch control, one at the head the other at the foot of the stairwell.

(j) Service and/or Feeder: Service to existing dwelling unit shall be a minimum of one hundred ampere, three wire capacity, service equipment shall be dead front having no live parts exposed whereby accidental contact could be made. Type "S" fuses shall be installed when fused equipment is used.

Exception: Existing service of fifty-five ampere three wire capacity, and feeders of thirty ampere or larger two or three wire capacity shall be accepted if adequate for the electrical load being served.

(k) Existing Wiring and Equipment: Existing wiring and equipment shall be in good repair. Circuit extensions made with flexible cord wiring in lieu of permanent wiring shall be eliminated.

1000–2. New Work. All new work shall conform to this ordinance.

1000–3. Evidence of inadequacy. Evidence of inadequacy shall be any of the following:

(a) Use of cords in lieu of permanent wiring.

(b) Oversizing of overcurrent protection for circuits, feeders or service.

(c) Illegal extensions to the wiring system in order to provide light, heat or power.

(d) Electrical overload.

(d) Misuse of electrical equipment.

(f) Lack of lighting fixtures in bathroom, laundry room, furnace room, stairway or basement.

Plumbing DWV Guideline for Residential Rehabilitation

I Prologue

Introduction

The Plumbing DWV Guideline for Residential Rehabilitation is intended to be used in all types of residential occupancies. It is not a code, but like a plumbing code, it is intended for use by persons knowledgeable about building plumbing design and installation. Its use should facilitate rehabilitation in circumstances where, for some reason, code requirements for new construction are being applied to the project undergoing rehabilitation. In general, there are two such circumstances:

- Repair and improvement of existing residential buildings, when compliance with the code requirements for new construction is triggered by a 25–50% Rule, or similar rule, which is in effect in the jurisdiction.
- Change of use or occupancy into a residential occupancy (e.g., from one- and two-family dwelling to apartment building, from office building to apartment building, etc.), when compliance with the code requirements for new construction is triggered by the provisions of the building code in effect, or some other provision.

In the latter circumstance (change of use or occupancy), this guideline should be used when it is feasible to reuse existing drainage, waste and vent (DWV) piping in the building, or when existing structural or architectural elements in the building pose physical constraints to the installation of new DWV piping.

Plumbing DWV requirements for new construction in building and plumbing codes are often viewed as major rehabilitation problems. Requirements to install new DWV systems in existing buildings which fully comply with current code provisions often lead to extensive additional structural and finish work. There are several aspects to this problem:

- Existing vent systems may not comply with prevailing code provisions for pipe sizing, connections, use of wet venting, and vent location, although they may provide adequate health and safety as installed and used.
- The installation of new vents and drainage lines, even for new fixtures, may be constrained by the limitations of available space and/or the installed configuration of the existing piping system.
- The cost-effective use of existing DWV systems in rehabilitation projects requires judgment and flexibility by the municipal building department to a greater extent and in a different manner than is required in new construction.

The plumbing DWV and related provisions in various codes, adopted by states and local jurisdictions, are not necessarily consistent with one another. What is permitted in one code may not necessarily be permitted in another. However, the hydraulic principles underlying the functioning of plumbing systems, and the potential health and sanitation hazards involved in DWV systems, are the same.

Alternative guideline solutions to various DWV installation problems typically encountered in residential rehabilitation are presented herein. The application of these guidelines is intended to provide a level of health and sanitation which is generally equivalent to the level intended by current plumbing code requirements, while reusing existing DWV elements as much as is feasible.

These guidelines are based upon accepted plumbing and hydraulic engineering principles in general practice, and upon the experiences of recognized testing facilities. The synthesis of such practices and experiences provides a sound basis for the necessary judgment and flexibility required for implementation of these guidelines.

Arrangement of the Guideline

Because the guideline recommends greater flexibility in meeting the health and safety intent of current codes, an understanding of basic drainage and hydraulic concepts is essential to its use. A general discussion of these concepts precedes the guideline itself.

The guideline is arranged as follows:

1. Determination of Existing Conditions of the DWV System
   - 1.1 Inspection, System Schematics and Preliminary Evaluation
   - 1.2 Testing the Existing System
     - a. Structural Serviceability
     - b. Hydraulic Integrity
     - c. Functional Performance
   - 1.3 Estimating the Capacity of the Existing DWV System
2. Problems and Solutions (Proposed Modification)
   - 2.1 Correcting Existing DWV System Structural, Hydraulic and Functional Defects, and Surcharged Sewers
   - 2.2 Relocating Fixtures
   - 2.3 Adding New Fixtures, Extending Existing DWV Systems and/or Installing New DWV System in Existing Buildings
   - 2.4 Through-the-Wall Venting

Appendix A: Performance Criteria
Appendix B: Examples of Acceptable Practices.

Basic Drainage and Hydraulic Concepts

Function of the Drainage System

The function of the DWV system is to collect spent water from the various building fixtures and drains and to convey this waste water to the public sewer or sewage treatment facilities in a safe and efficient manner.

A "safe manner" means collection and transmission without the emission of sewer gases, foul odors, or suds into the inhabitable area of the building. Traps at the entrances to the DWV system provide water seals which prevent the escape of sewer gases. Most codes limit the pressure fluctuation within drainage systems to plus or minus 1-inch of water pressure under design load conditions. A more practical limitation, and the one used in this guideline, is *to limit the trap seal reduction to 1-inch of water under normal conditions of loading.* Acceptance of this concept permits the planning and carrying out of simple field tests on existing systems to determine

their condition, and to provide a basis for approving modified systems in rehabilitated buildings.

An "efficient manner" means the conveyance of waste water and suspended solids without blockage. Efficient transport is a function of both velocity and depth of flow. The generally accepted criteria to ensure efficient performance is to size the horizontal drainage lines such that the velocity of flow is approximately 2 feet per second.

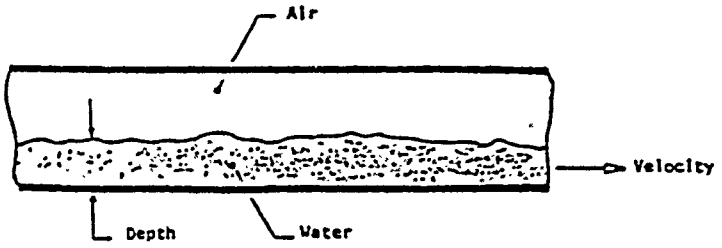
If the depth is not sufficient, solids will settle out. The depth of flow and water velocity are both influenced by the slope or pitch of the drain line. Increasing the slope from ⅛-inch per foot to ¼-inch per foot increases the velocity of the water while it decreases the depth of flow. Knowledge and understanding of these characteristics of flow provides the basis for adjusting the slope of existing building drains, which often determines the capacity of the plumbing drainage system.

Hydraulic Principles

The rate and volume of discharged spent water from plumbing fixtures and drains, as well as the frequency of fixture use, are important variables to the understanding of the functioning of the DWV system. Frequency of fixture use is high in public buildings, such as stadiums and theaters, and low in residential buildings. All fixtures will not operate simultaneously. Estimating fixture use in residential buildings requires only an estimate of the maximum number and combination of fixtures that may discharge simultaneously. In larger buildings, the fixture unit concept is employed. Existing DWV piping systems are not normally loaded to capacity; therefore, they will usually accept a limited number of additional fixtures without seriously decreasing the system's performance. The rate at which water exits from plumbing fixtures changes continuously. For water closets, the discharge typically begins a few seconds after the flush is started and gradually rises to a peak rate of approximately 30 gallons per minute, remaining constant for a few seconds and then gradually falling to zero. The use of water saving closets does not increase drainage problems since their peak discharge rate is similar to conventional fixtures. The discharge time for a typical lavatory is approximately 12 seconds and the peak flow rate is about 10 gallons per minute. This low flow rate and short duration suggest that lavorities have only a small influence on the functioning of the DWV system. Bathtub discharge is influenced significantly by the geometry of the outlet piping, and may have a significant effect due to its long duration. In most outlet arrangements, the rate of discharge rises to approximately 12 gallons per minute almost instantly and thereafter decreases continuously as the tub drains. Water conserving shower heads reduce flow rates, and thereby improve the effects of bathtub discharge characteristics on the DWV system.

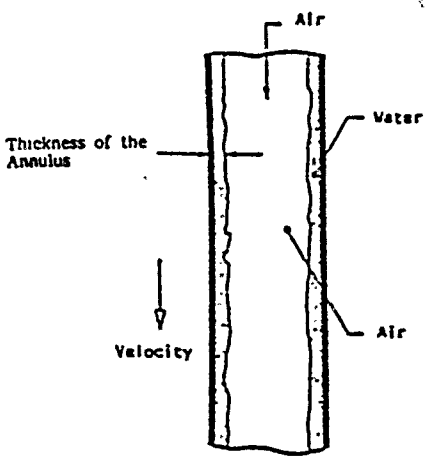
Flow in Drains and Stacks

The flow of spent water in horizontal drainage systems may ber described as separated flow since the horizontal drain is generally only partially filled. Water moves through the lower part of the pipe, while air flows through the upper part.



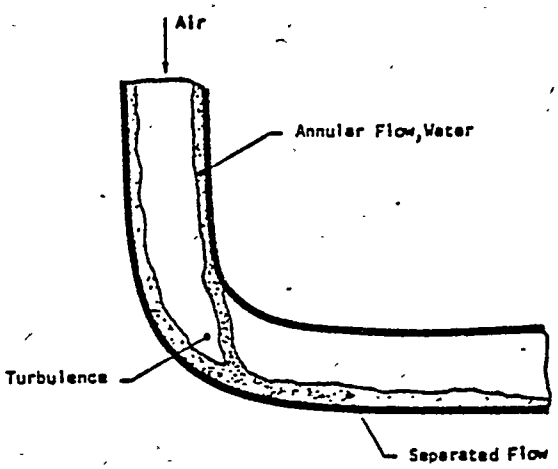
The velocity and depth of the water flow in horizontal drains continually changes. As the volume of water increases, the depth of flow also increases, displacing the air above it. When most of the air space is filled with water, turbulence increases significantly, and even small water pulsations disturb trap seals in the system's plumbing fixtures. Therefore, horizontal drains are designed to flow no more than half full.

The flow in vertical drains or stacks is entirely different. As water enters the stack it attaches itself to the walls of the pipe, forming an annulus. This cylinder of water falls down the pipe, dragging air with it.



The establishment of annular flow is rapid. It occurs within several feet of the point where the water enters the pipe. Increasing the volume of water increases the annulus thickness. When the volume of water occupies approximately ⅓ of the cross-sectional area of the pipe the annular flow breaks down, causing extreme turbulence and pulsations which may result in the loss of trap seals. Small diameter vertical pipes close to fixture outlets are susceptible to breakdown of the annular flow which may result in self siphonage of the fixture. It is for this reason that S traps have been prohibited by codes.

The most critical area in a drainage system is at the base of the stack. In this region the flow must change from the annular flow of the stack to the separated flow of the horizontal drain.



The disturbance at the base of the stack may be large, and significant positive pressures may be generated which, if not relieved, cause blowback—the reversed passage of water through the trap. If the transition is smooth, much of the air is carried away through the horizontal drain.

Horizontal drains are not able to transport spent water at the same velocity as stacks. This results in a phenomenon called hydraulic jump. The change in velocity from approximately 15 feet per second in the stack to 2 feet per second in the horizontal drain forces an increase in the depth of flow. Recently it has been found in laboratory tests that this rise in the water level occurs much further downstream than the generally accepted 10-pipe diameters. What has been observed in the immediate vicinity of the base of the stack is a washing of the sides of the drain which may cause temporary blockage of fixture drains or vents that enter nearby. Fittings rolled up to 45 degrees are effective in avoiding problems in this area.

Modes of Trap Failure

The traps of a drainage system may fail by one or more of the following means:

- *self-siphonage,* or reduction of the trap seal as a result of siphonic action by the discharge of the fixture to which the trap is connected
- *induced siphonage,* or reduction of the trap seal as a result of siphonic action by discharge of fixtures other than the one to which the trap is connected
- *blowback,* or the emission of water, air, sewer gas or suds into the fixture or the inhabited area of the building through the fixture trap
- *cross-flow,* or the movement of waste water from the trap, trap area or branch drain of an operating fixture to the trap, trap area or branch drain of an idle fixture.

The first of these modes of failure, self-siphonage, is a function of fixture and branch piping characteristics. Plumbing fixtures which exhibit a sharp fall off in flow, such as round bottom lavatories, are more sensitive to self-siphonage than those with more gradual changes in flow. Traps serving bathtubs are rarely subject to self-siphonage. Self-venting trap arms and branch drains can be designed to prevent self-siphonage through knowledge of the fixture discharge characteristics and correct pipe sizing and configuration.

Induced siphonage, blowback and cross-flow are prevented through correct venting design and installation. Every drainage system has a basic hydraulic capacity which may be increased by the addition of vents. The function of venting is to maintain close to atmospheric pressure in the drainage system so that trap seals will not be disturbed. A sure way to protect the DWV system is to provide individual fixture vents, an obviously expensive approach. Among the more economical alternatives that have been developed, tested and commonly approved for residential buildings are stack venting and wet venting.

In stack venting, fixture traps are protected by venting provided through the upper portion of the soil or waste stack. Successful installations require that fixtures be connected to the stack independently, in the order of their rate of discharge (those with the highest rate of discharge placed at the lowest point in the module), and at those parts of the stack where the pressure fluctuations are small. Most codes allow stack venting of fixture traps on the top floor of a building.

Wet venting is a technique that uses the drainage pipe itself for venting of selected fixture traps. In practice, wet vents receive only the spent water from fixtures that have a low rate of discharge. These fixtures need not enter the stack independently, and in many installations groups of fixtures connect to a single horizontal branch. A variety of wet vented modules have been developed and accepted by various codes over the years.

Progressive plumbing designes incorporate wet vented and stack vented modules as major DWV

components, supplemented by individually vented fixtures where required by design restraints.

II Guideline

1. Determination of Existing Conditions of the DWV System

In the process of determining the need for and extent of building rehabilitation involving the plumbing DWV system, and of submitting such proposed rehabilitation work to a building department, it will be necessary to determine the existing conditions of the DWV system in the building. This determination is needed by the building owner and designer, as well as by the building official who may need more information about the work to be done (see *Guideline for Approval of Building Rehabilitation).*

This part of the guideline contains discussions of inspection procedures, documentation, testing and methods for estimating system capacity which may be required to determine existing conditions.

1.1 *Inspection, System Schematics and Preliminary Evaluation.* A field inspection of the existing DWV system should be carried out to provide the following general information:

- Overall physical condition of the system.
- Evidence of impaired structural serviceability and hydraulic integrity of parts of the system.
- Configuration and sizing of the system.
- Existence of surcharged sewers.
- Rehabilitation program requirements affecting building structural and architectural elements, as well as the DWV system.

Based upon this inspection, and in conjunction with data from any available plumbing construction drawings and specifications, a schematic diagram of the DWV system should be prepared. Such a diagram will provide information necessary for establishing the following:

- Scope of the system and related building elements.
- The need for modification or amplification of the functional performance test discussed in 1.2 below, and the number of tests to be performed.
- Calculation of the installed capacity and the code-permitted capacity of the installed DWV system, discussed in 1.3 below.

1.2 *Testing the Existing System.* a. *Structural Serviceability.*—In most cases, physical testing to determine structural serviceability of the DWV system is unnecessary. Adequate evidence related to structural serviceability may be obtained by the following:

- Careful attention to those areas where the DWV system is exposed to view.
- Evidence of exposure to freezing temperatures.
- Evidence of fire damage.
- Careful attention to the DWV system's attachments to, and penetrations of, the building structure.

b. *Hydraulic Integrity (Watertightness).*—In addition to the inspection for hydraulic integrity, when all evidence of leaks is to be noted, one or more of the following tests should be performed to determine the watertightness of the DWV system and to locate leaks, if any.

If the DWV system and connected fixtures are intact, perform the *Finished Plumbing Test* described below, keeping in mind that the test method involves a thick pungent smoke, and may be impractical or difficult to perform in a partially occupied building.

If the Finished Plumbing Test cannot be performed on the intact system, perform the *Flow Test* described below.

If the DWV system is not intact, perform the *Rough Plumbing Test* described below.

Each of these tests provides evidence on the watertightness of the DWV system. If the DWV system has been in recent and continuous use and has not developed any leaks, and if the proposed rehabilitation is not extensive, consideration should be given to performing no tests for hydraulic integrity.

Where available, standard test procedures included in the local plumbing code should be followed for each of the tests briefly specified as follows:

Finished Plumbing Test. The test of intact DWV system should be performed by filling all traps with water and then introducing into the system, near the base of the stack, a thick pungent smoke. When the smoke appears at the vent openings, they shall be closed and a pressure equivalent to a 2-inch water column attained. This pressure shall be held for 15 minutes before inspection starts.

Flow Test. The flow test should be performed on all parts of the intact DWV system by filling each fixture within a group to its normal capacity and then discharging the spent water. Where several fixtures are connected to the same branch, the fixtures shall be discharged together.

Rough Plumbing Test. The water or air test conducted on the roughed-in plumbing shall be completed by blocking the lower portion of the system and filling the drainage and vent piping with water. In tall buildings the system should be tested at intervals such that the manufacture's working pressure for the joints is not exceeded, but no section should be tested with less than 10 feet of water except the uppermost 10 feet of the system. The water shall be kept in the system for at least 15 minutes before the inspection starts. The system shall be tight at all points. When using air as a test media, all inlets and outlets must be sealed except where the air pressure apparatus is connected to the system. Air shall be forced in until a uniform gauge pressure of 5 psi is attained. This pressure shall be held for 15 minutes without the introduction of additional air.

c. *Functional Performance.*—DWV systems with proven hydraulic integrity (i.e., proven in accordance with b. above, or repaired in accordance with Section 2.1 of "Problems and Solutions" below) should be subjected to one or more functional performance tests unless they are in compliance with current codes (see 1.3 below). Functional performance tests should be carried out in order to determine the DWV system's resistance to the following modes of failure:

- self-siphonage
- induced siphonage
- blowback
- cross-flow

Test for self-siphonage, and tests for induced siphonage, blowback and cross-flow which may occur on the same floor (i.e., branch pipe testing) should be planned on the basis of analysis of the system schematics discussed in 1.1 above. Tests for resistance to induced siphonage and blowback on different floors (i.e, stack testing) should be carried out for each stack.

The following clear water test is appropriate for back to back bathroom stacks up to ten stories in height. (Increased test loads, introduction of solids and/or suds, and other points of observation should be considered for other types of stacks, based on analysis of the system schematic.):

Functional Performance Test for Bathroom Stacks: (1) Select the required test load from the table below. The test loads are based upon a frequency of the use ratio of 0.01. This frequency of use is consistent with experiences at Davidson Labortory and at the National Bureau of Standard (see Table A5, NBSIR 73-161, "*Field Test of Hydraulic Performance of a Single-Stack Drainage System at the Operation BREAKTHROUGH Prototype Site in Kings County, Washington* "),

and is significantly lower than the test loading requirements of Ch. XVI, Standard Plumbing Code, and British test loading data. For different frequency ratios and related loading requirements, see Table A5 referenced above.

Building Type and Test Load

Single family dwelling—One water closet and one bathtub
Multi-family up to four stories—Two water closets
Multi-family four to ten stories—Two water closets and one bathtub

The fixtures selected for discharge should be those most remote with respect to the building drain in single family homes, and vertically adjacent at the uppermost levels in multi-family dwellings.

(2) Fill all fixture traps. Discharge the selected fixtures simultaneously. Observe and record the trap seal reduction in the idle fixture traps. Reduction of more than one-inch of water is critical and should be recorded. Observe the lower floor water closets for blowback.

Performance tests like the one specified above, carried out in the laboratory on full-scale drainage systems, have shown that trap seal reduction by induced siphonage is greatest in those fixtures located two and three floors below the active fixtures. Blowback, the most common mode of failure, usually is observed in the ground or first floor water closets. Systems near capacity will show trap seal reduction of ¾" to 1" and/or display considerable movement of the water surface in the closets.

Despite extensive experience with laboratory testing, and the inclusion of performance test guidelines in the Standard Plumbing Code (Ch. XVI), standard test instrumentation and procedures have not been developed for performance testing of plumbing systems. If and when such standard methods are developed, the performance testing recommended above should be carried out in accordance with such methods.

1.3 *Estimating the Capacity of the Existing DWV System.* The installed capacity of the existing DWV system should be estimated for two reasons. First, by comparing it to the code-permitted capacity of the installed DWV system, potential code-related problems will become evident. Second, the estimate of the capacity can be used directly in suggesting the system's potential for accepting additional fixtures to be installed as part of the proposed rehabilitation.

The following procedure should be followed:

(1) I identify and count all fixtures connected to each DWV stack. Translate the fixture count into fixture unit values, based on the following table:

Fixture:	*Fixture units*
Automatic clothes washer	3
Bathtub(w/or w/o Overhead shower)	2
Bathroom group (incl. tank type water closet)	6
Bathroom group (incl. flushometer valve water closet)	8
Dishwasher	2
Floor drain	2
Kitchen sink (w/ or w/o food-waste grinder)	2
Lavatory	1
Laundry tray	2
Shower stall	2
Sink, service type with floor outlet	3
Sink, service type with P-trap	2
Water closet (tank type)	4
Water closet with flushometer valve	8

(2) Based on the system schematic (1.1 above) identify the existing size of the stack and size and slope of the drain, as well as code required sizes.

(3) Based on the system schematic (1.1 above) determine the type of venting. For the purpose of simplification, the type of venting falls into three categories: single stack with no secondary vents, vents of "unknown" condition, and code-complaint vents.

Vents of "unknown" condition are vents which may be partially blocked, or are otherwise of lesser venting than code-complaint vents.

(4) Based on (2) and (3) above, estimate the fixture unit capacity of the DWV system from the following table (note that this table applies to back to back vertical stack arrangements only):

Stack size	Building drain size @ ¼" slope[1] per foot	Allowable number of fixture units: Single stack[2]	Vents of "unknown" condition[3]	Code-complaint vents
3"	4"	[4]15	[4]30	[4]72
4"	4"	96	150	216
4"	5"			480
5"	5"			480
5"	6"			840

[1] If slope exceeds ¼" per foot, capacity will increase.
[2] Capacity of single stack as found in an existing building. This capacity may be exceeded with engineered single stack systems subjected to final performance tests. Single stack systems are not recommended in locations where building drains are subject to flooding under normal conditions.
[3] The listed capacities may be exceeded if the system does not fail when subjected to final performance tests.
[4] Not more than 3 stories, nor more than 6 water closets.

2. Problems and Solutions (Proposed Modifications)

2.1 *Correcting existing DWV system structural, hydraulic and functional defects, and surcharged sewers.*

(1) *Problem.* Based on the inspection of the existing DWV system (1.1 above), it is determined that the mechanical strength of existing pipes, fittings and supports is appreciably lower than that required for new construction and/or the DWV system is inadequately attached to the building. These conditions may be evidenced by:

- extensive corrosion, scale and other deterioration of wall thicknesses; pipe movement, misalignment, nonuniform slope;
- joint separation;
- other indications of failure;
- evidence of exposure to freezing temperatures;
- evidence of excessive thermal expansion and contraction;
- evidence of fire damage.

Solution. Removal or repair of the damaged parts.

Discussion. Age alone is not indicative of the condition of a plumbing drainage system. Many systems have been found to be in excellent physical condition after decades of service.

(2) *Problem.* Observed reduction of clearances in sleeves and supports, pipe deflection, or other evidence, indicates that the DWV system has been subjected to excessive live or dead loads, above normal service loads.

Solution. Remove such live or dead loads and repair or replace damaged parts.

(3) *Problem.* When subjected to any of the three tests for hydraulic integrity discussed in 1.1.b. above (Finished Plumbing, Flow, or Rough Plumbing Tests), any part of the DWV system is not watertight.

Solution. Repair or remove parts of the DWV system as needed to bring it to a condition of watertightness under the subject tests.

(4) *Problem.* When subjected to any of the functional performance tests as discussed in 1.2.c. above, trap seal reduction of more than one-inch of water (induced siphonage), and/or blowback, self-siphonage or cross-flow are observed in the DWV system, indicating functional deficiency.

Solution. Modify the DWV system, in accordance with Section 2.3 of this guideline, to a condition where it meets all the functional performance tests (see also the Basic Drainage and Hydraulic Concepts section of the Prologue).

(5) *Problem.* Self-siphonage is observed in an S trap that is subjected to a functional performance test.

Solution. Modify the fixture so that the distance between the trap outlet and the vertical drop is at least two pipe diameters but only if the size of the vertical pipe is one diameter larger than the trap inlet. See also Figure 1 of Appendix B for additional information on acceptable practices.

Discussion. The concern for self-siphonage of S traps has led to their prohibition by codes. Self-siphonage in S

traps can be eliminated by the modification described above, which is consistent with National Standard Plumbing Code, 12.8.2.

(6) *Problem.* The inspection reveals that the drainage system of the building is subject to backflow from the public sewer system.

Solution. Approved suitable means such as sewage ejectors, isolation of basement drainage and backwater valves should be employed to prevent backflow from entering the building.

2.2 *Relocating fixtures*

Problem. The proposed rehabilitation, when the existing DWV system is without structural, hydraulic or functional defects (as determined in 1.2 above), and has adequate capacity for its installed fixtures (as determined in 1.3 above), involves the relocation of fixtures without additional load imposed on the system. However, the proposed new fixture location, and the location of existing vertical drain to service that fixture, requires a length of horizontal fixture drain which, if unvented, will exceed that allowed by the local plumbing code.

Solution. For bathroom groups, allow fixture drain lengths at a slope of ¼" per foot, up to the maximum indicated in the following table, provided the connection to the stack is with a sanitary tee or a long turn TY:

Maximum Developed Length of Unvented Fixture Drains

Diameter of drain and length: 1¼ inches—5 feet; 1½ inches—7 feet; 2 inches—10 feet; 3 inches—12 feet; 4 inches—20 feet.

For kitchen (flat bottomed) sinks with or without dishwasher and garbage disposer, allow drain lengths, at a slope of ¼" per foot, up to 12 feet with 2" drain (see illustrations, Appendix B).

Discussion. The concern for self-siphonage in fixtures has led to limitations on lengths of unvented fixture drains. Existing distances as specified in codes may impose a severe restriction on rehabilitation. The smaller diameter fixture outlets of modern installations have reduced flow rates and suggest longer permissible fixture drains.

The data in the table above is based on the following reports: "*Test on Branch Layouts—Investigation of Minimal Tube Diameter*", by O. H. C. Messner, Zurich, Switzerland, April, 1970; and "*An Investigation of the Safety and Durability of the Plumbing Systems in Mobile Homes*", Report SIT-DL-79-9-2079, Stevens Institute of Technology, Hoboken, N. J. (to be published).

Recommended kitchen unit drain lengths are based on "*Plumbing Manual*", BMS-66, U.S. Government Printing Office, 1940.

2.3 *Adding new fixtures to existing DWV systems, extending DWV systems, and/or installing new DWV systems in existing building*

Problem. The proposed rehabilitation, when the existing DWV system is without structural, hydraulic or functional defects (as determined in 1.2 above), involves any combination of the following activities:

- adding new fixtures to the existing DWV system when its capacity exceeds its installed fixtures (as determined in 1.3 above);
- extending the existing DWV system when its capacity exceeds its installed fixtures (as determined in 1.3 above);
- installing new DWV systems in an existing building (whether or not the existing system will continue in use).

However, full compliance with current plumbing codes may lead to extensive sturctural or architectural changes that result in unwarranted additional costs and delays to the rehabilitiation project.

Solution. All additions and alterations to existing plumbing DWV systems should be designed and installed in accordance with Performance Criteria covering the following attributes of the system: (1) Transport of wastes; (2) Durability; (3) Maintainability; (4) Structural serviceability; (5) Hydraulic integrity; (6) Functional performance.

The Performance Criteria are included in Appendix A below.

Alternative acceptable solutions may be found in the following documents, referenced specifically herein:

- Standard Plumbing Code, Chapter XVI, Section 1602—Single Stack Discharge Ventilating Pipe Systems.
- SBCCI and BOCA Research Reports, for automatic anti-siphon trap vent devices.
- NBS BSS-60, "hydraulic Performance of a Full Scale Townhouse System with Reduced-Size Vents", August 1975, for reduced sized venting design.

Appendix B illustrates typical solutions which will comply with the Performance Criteria under most conditions of operation and use, based on engineering analysis and interpretation of test results.

Discussion. Single stack DWV systems, even if complying with the Performance Criteria, are not recommended in locations where building drains are subject to flooding under normal conditions.

2.4 *Through-the-Wall Venting*

Problem. An existing DWV system, an addition to an existing DWV system or a new DWV system in an existing building, may include through-the-wall rather than roof venting. This condition may be determined by inspecting the building or examining existing and/or proposed plans, and is likely to be prohibited by the local code.

Solution. Through-the-Wall venting should be accepted in the following instances:

(a) In historic building where through-roof venting would interfere with the character of the building.

(b) In rehabilitation projects where conventional venting is impractical. In this case, the vents should be at least ten feet horizontally from the lot line and should be turned downward. They should be effectively screened with ¼ inch mesh, to avoid trapping and freezing of any condensation. Through-the-wall vent openings should not be located directly below any door, window or other building opening, nor should any such vent terminal be within ten feet horizontally of such an opening unless it is two feet above the top of such opening.

Appendix A—Performance Criteria

The following Performance Criteria are referenced in Problem 2.3 above.

(1) *Transport of Wastes*

Requirement. Waste water and sewage shall be removed from the building and transported to an acceptable point of disposal without overflowing, accumulating, or backing up into fixtures.

Criteria

(a) Drainage stacks shall carry design loads when flowing less than ⅓ full at terminal velocity.

(b) Horizontal branch drains, and building sewers except horizontal fixture drains, shall flow no more than approximately ½ full under design loads. Horizontal fixture drains shall be sized to give an optimum balance between scouring velocity, diameter and carrying capacity.

(c) Maximum lengths of unvented fixture drains, at a slope of ¼" per foot, shall be in accordance with the table in 2.2 above.

(d) Waste lines likely to carry grease (especially kitchen lines of 2" diameter or less) shall not pass through spaces where they may be subjected to temperatures below the ambient temperature of the occupied space, and all waste lines shall not be subjected to freezing temperatures, unless they are adequately protected.

(e) Vents shall not connect to horizontal drains unless the bases of such vent connections are washed by the discharge from one or more small fixtures.

(f) A uniform, continuous grade of the invert of horizontal drain lines shall be provided.

(g) Fittings, devices, connections and methods of installation shall not obstruct or retard the normal flow of fluids in soil, waste or vent lines.

(h) Waste water or waterborne solids from an active drain pipe shall not pass through an idle trap to a fixture.

(i) Suitable means shall be provided for handling drainage below sewer level. Drainage from parts of drainage systems which cannot drain by gravity into the sewer shall be disposed of through a separate drainage and sewage ejector system, and discharged into the building gravity drainage system.

Test. Determination of conformance to criteria by evaluation of calculations, plans and specifications, inspection of built elements, and conformance to good engineering and trade practices.

Discussion. These criteria have been derived from experience and research on plumbing hydraulics at the Davidson Laboratory, Stevens Institute of Technology, or from standard design practice in general acceptance.

(2) *Durability*

Requirement. The plumbing DWV system and its parts shall have a life expectancy as determined by the local jurisdiction.

Criteria

(a) New plumbing DWV equipment and systems shall be made of materials approved for new construction, free from defective workmanship, and designed and installed so as to be durable, without need for frequent repairs or major replacements.

(b) Before proceeding with an installation, the installer should consult with the local Building Department to determine the durability of materials and joints used under local conditions.

(c) The installer should observe the manufacturer's good practice recommendations regarding handling, storage, installation and adjustment of materials and equipment so that the performance of such products will not be impaired by defects or damage.

Test. Determination of conformance to criteria by inspection of installation and materials, and conformance to good trade practices.

(3) *Maintainability*

Requirement. The design and installation of the DWV system shall provide for cleaning, servicing, adjusting or replacing the various elements, and shall minimize conditions that contribute to soiling, deposition, fouling, clogging, or other maintenance problems.

Criteria

(a) Horizontal drains shall be installed in uniform alignment at a slope in the direction of flow of at least ¼ inch per foot for diameters of 4 inches and greater, to obtain self-scouring velocities. Where such slopes are not attainable, lesser slopes may be used if a mean velocity of at least 2 feet per second can be computed for open channel steady flow at an assumed depth equal to ½ of the diameter.

(b) Access to permit convenient removal of obstructions and fouling matter in horizontal drain lines shall be provided as follows:

- not more than 100 feet apart for larger pipes;
- at each change of direction of the building drain in excess of 45°;
- at or near the foot of each vertical soil or waste stack;
- near the junction of the building drain and building sewer.

Test. Determination of conformance to criteria by evaluation of calculations, plans and specification, inspection of built elements, and conformance to good engineering and trade practices.

(4) *Structural Serviceability*

Requirement. The DWV system shall be capable of withstanding the physical forces that may reasonably be expected in the building during the rehabilitation process and in subsequent use.

Criteria

(a) The mechanical strength of new pipe, fittings and supports shall be similar to that of new construction.

(b) The DWV system elements shall be securely attached to the building.

(c) DWV piping shall not be subject to dead or live loads above normal service loads.

Test. Evaluation of installation.

(5) *Hydraulic Integrity*

Requirement. The drainage, waste and vent system shall be air and water tight under conditions of *normal use.*

Criteria

(a) The major elements of the DWV system (building drains, stacks and horizontal branches) shall be leak tight when subjected to a pressure of 5 psi.

(b) The completed DWV system shall be leak tight when subjected to a pressure equivalent to a 2-inch water column.

Test

(a) *Rough Plumbing Test.* See test specified in 1.2.b. above.

(b) *Finished Plumbing Test.* See test specified in 1.2.b. above.

(6) *Functional Performance*

Requirement. The DWV system shall accept and transport spent water and liquid in a safe and efficient manner.

Criteria

(a) The DWV system shall not, under conditions of normal use, display any of the following failures:

- self-siphonage at any fixture trap
- trap seal reduction greater than one inch, indicating induced siphonage
- evidence of blowback at any fixture
- ejection of suds at any fixture
- evidence of cross-flow in any branches of back to back fixtures.

(b) Single stack DWV systems shall be deemed to conform to this performance guideline if designed in accordance with Section 1602, Chapter XVI of the Standard Plumbing Code.

(c) Automatic anti-siphon trap vent devices may be used in the DWV system, as permitted by model code having jurisdiction, and shall be in conformance with the applicable SBCCI and BOCA Research Reports.

(d) Reduced sized venting may be used in the DWV system of buildings under three stories in height, provided that the entire system shall be designed by a qualified professional engineer, in accordance with criteria and guidelines contained in the NBS publication, Building Science Series-60, "Hydraulic Performance of a Full Scale Townhouse System with Reduced-Sized Vents", August 1975.

(e) Code-accepted proprietary, engineered single sack DWV systems shall be designed and installed in accordance with the conditions of their acceptance.

Test

(a) *Functional Performance Tests.* See discussion in 1.2.c above.

(b) Evaluation in accordance with Chapter XVI, Standard Plumbing Code.

(c) Evaluation in accordance with applicable SBCCI or BOCA Research Reports.

(d) Evaluation in accordance with BSS–60.

Discussion. Compliance with this requirement can always be achieved by the addition of supplemental venting in DWV systems failing this test.

Appendix B

Examples of Acceptable DWV Practices for Building Rehabilitation

The following illustrated DWV practices have been determined to be adequate in solving problems of the type discussed in this guideline, based on engineering principles and the experience of recognized testing facilities. They do not represent all possible problems, nor do they reflect

the most extreme solutions in terms of deviation from the specific requirements of plumbing codes.

Symbols

WC, water closet; T, bathtub; L, lavatory; KS, kitchen sink; ———, new sanitary piping; ————————, existing sanitary piping; ———, vents.

BILLING CODE 4210-01-M

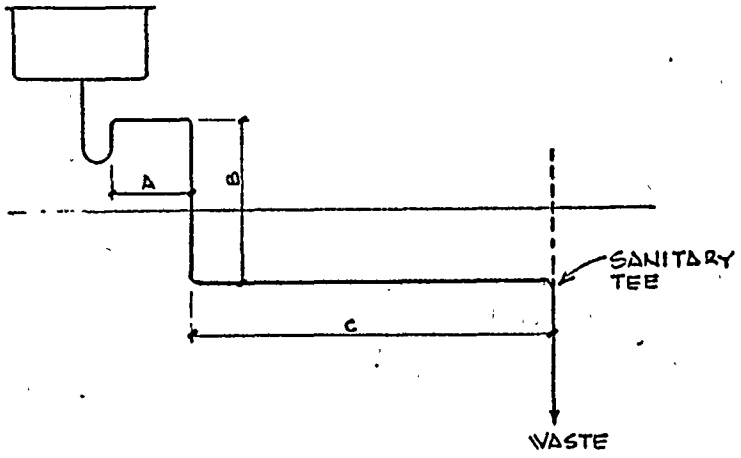


Figure 1

CORRECTION OF "S" TRAP SUBJECT TO SELF-SIPHONAGE IN FLAT BOTTOMED SINKS

Illustration of solution to problem 2.1(5).

A = not more than 10 pipe diameters
B = not more than 24 pipe diameters
C = not more than 72 pipe diameters

- all pipe 2" diameter
- 1½" trap

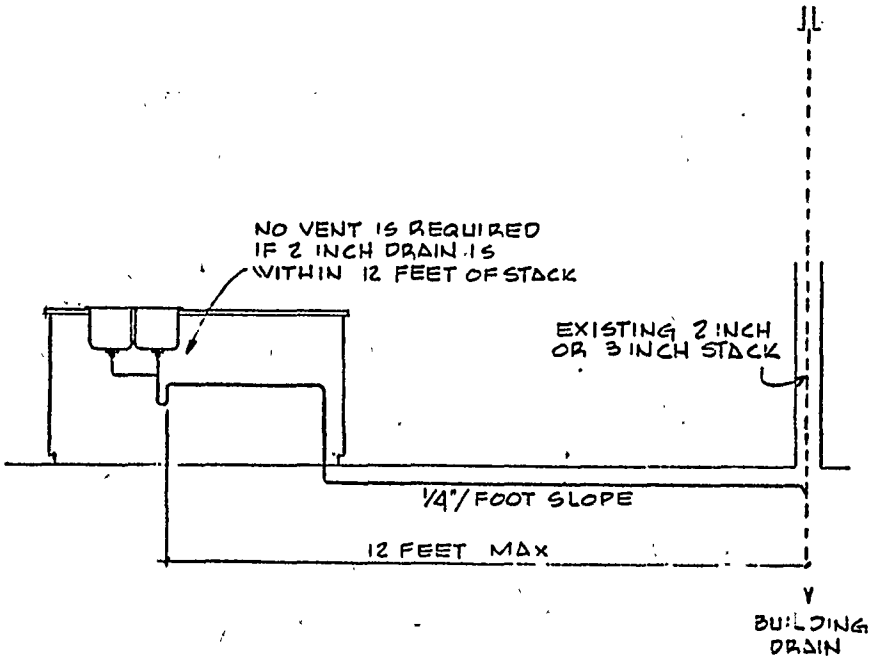


Figure 2

ISLAND SINK

Example of solution to problem 2.2.

- all pipe 2" diameter
- 1½" trap

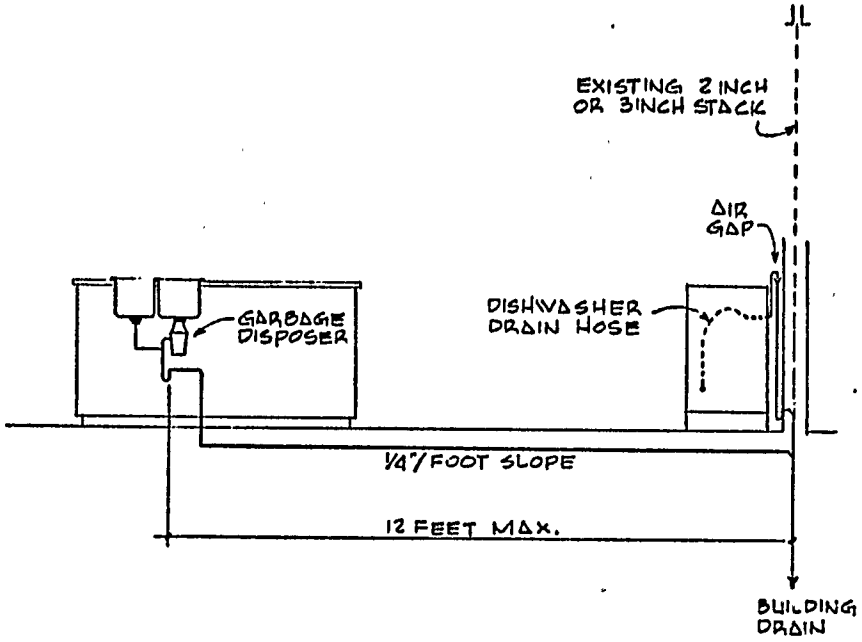


Figure 3

ISLAND SINK WITH DISPOSER AND DISHWASHER AT WALL

Example of solution to problem 2.2.

Note that required location of dishwasher air gap may vary by local code.

- all pipe 2" diameter
- 1½" trap

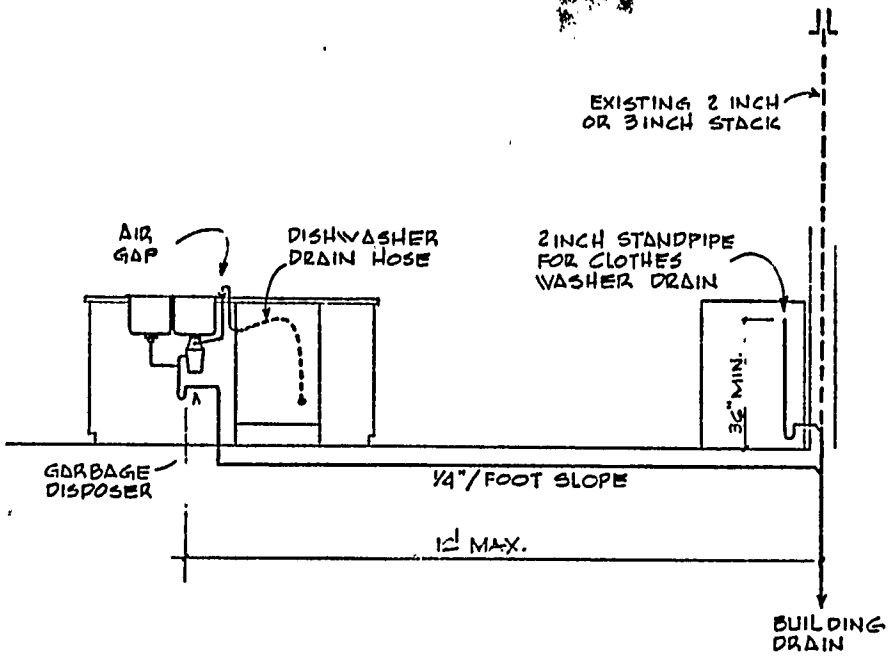


Figure 4

ISLAND SINK WITH DISPOSER, DISHWASHERS, AND CLOTHES WASHER AT WALL

Example of solution to problem 2.2.

Note that required location of dishwasher air gap may vary by local code.

- all pipe 2" diameter
- 1½" trap

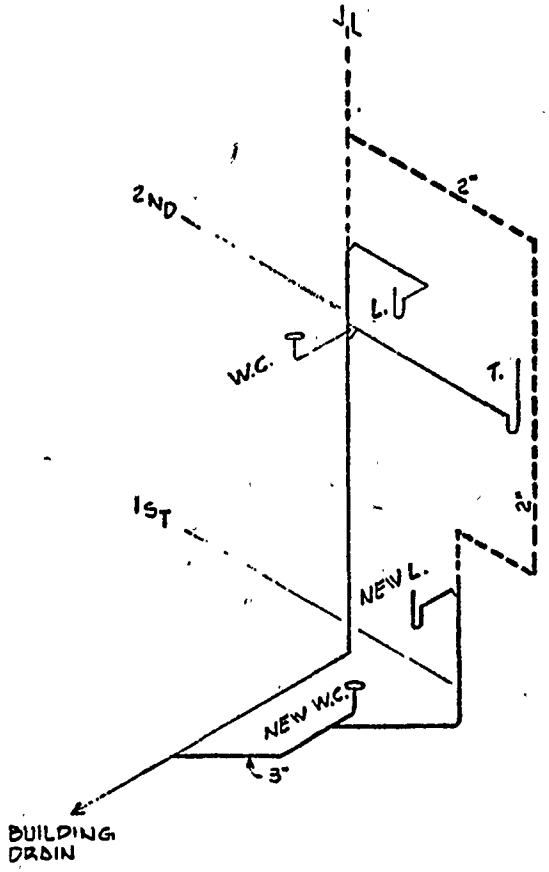


Figure 5

ADDITION OF FIRST FLOOR POWDER ROOM OF SINGLE DWELLING UNIT, SLAB ON GRADE

Illustration of use of wet venting in solving a problem of the type discussed under 2.3. For possible use of single stack solutions, see 1.3(4) and discussion under 2.3.

Note that new branch drain line may enter building drain on stack.

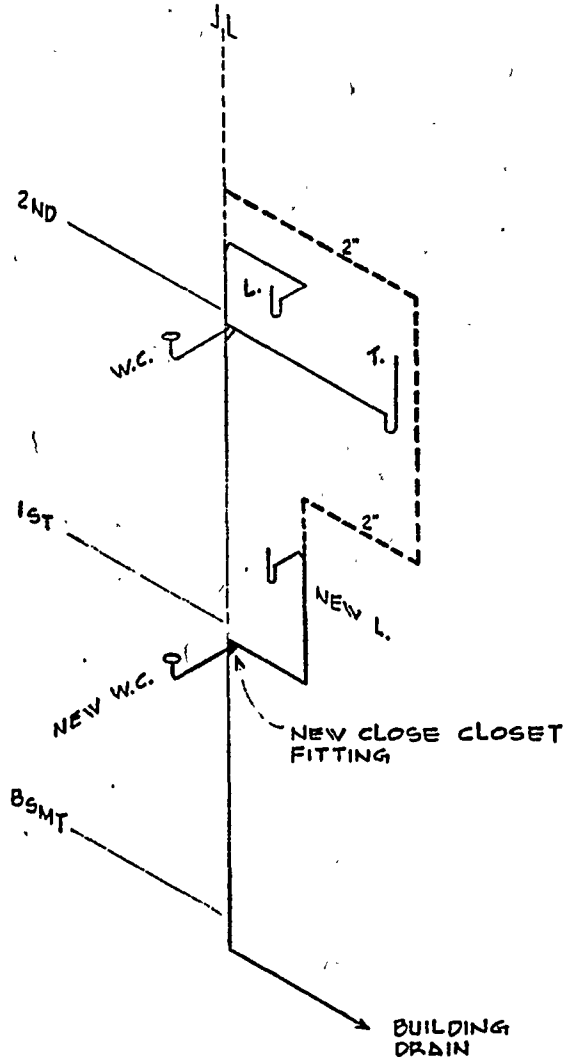


Figure 6

ADDITION OF FIRST FLOOR POWDER ROOM OF SINGLE DWELLING UNIT, WITH BASEMENT

Illustration of use of wet venting in solving a problem of the type discussed under 2.3. For possible use of single stack solutions, see 1.3(4) and discussion under 2.3

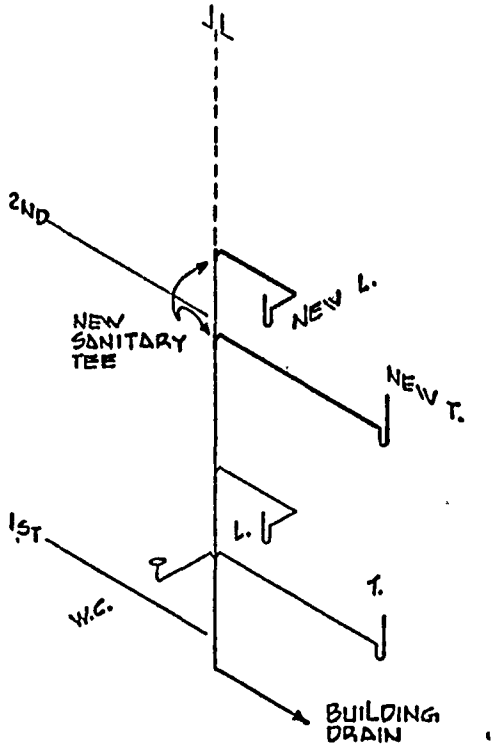


Figure 8

ADDITION OF SECOND FLOOR FIXTURE TO EXISTING STACK

A second kitchen sink, with or without disposer, may be added to an existing 2 inch waste stack. A 1½ inch fixture drain may run 7 feet maximum.

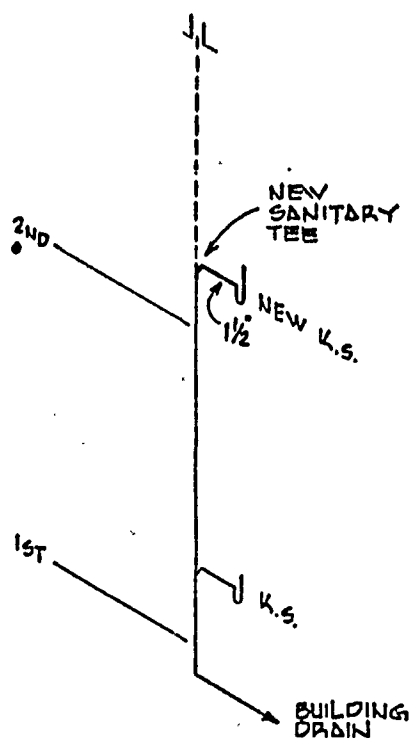


Figure 7

ADDITION OF SECOND FLOOR FIXTURE TO EXISTING STACK

A lavatory and bathtub may be added to the second floor of a stack vented bathroom group. Two inch diameter tub drain may run 10 feet maximum.

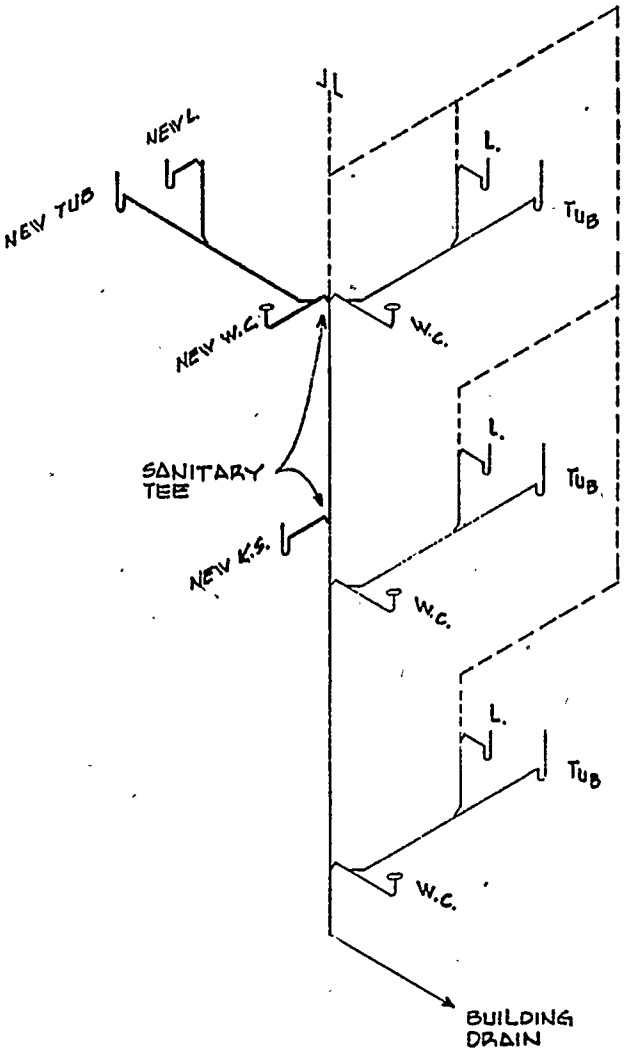


Figure 9

ADDITION OF KITCHEN SINK AND BATHROOM GROUP TO EXISTING 3-STORY STACK

Illustration of use of stack venting in solving a problem of the type discussed under 2.3

Kitchen sinks or bathroom groups may be added to an existing wet vented stack (4" stack required). of not more than three floors in height.

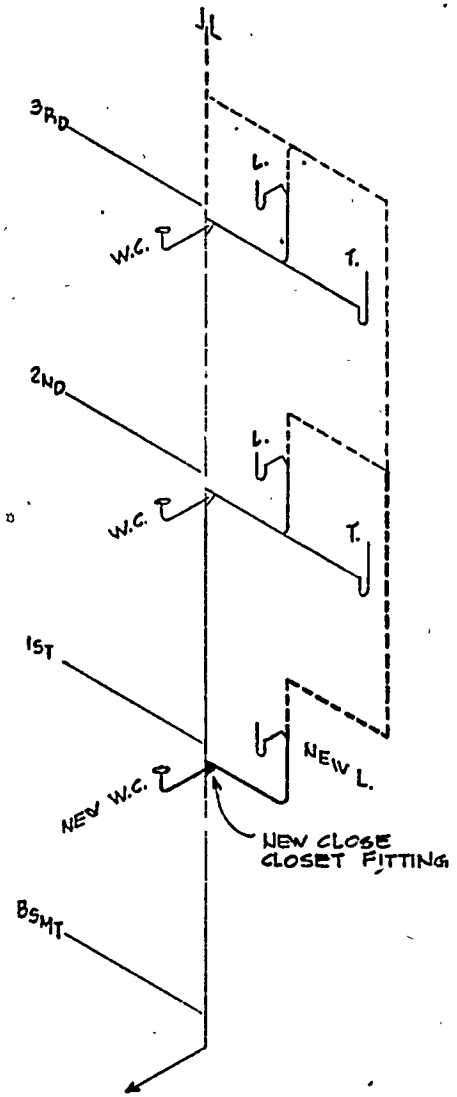


Figure 10

ADDITION OF FIRST FLOOR POWDER ROOM TO EXISTING 3-STORY STACK

Illustration of use of wet venting in solving a problem of the type discussed under 2.3.

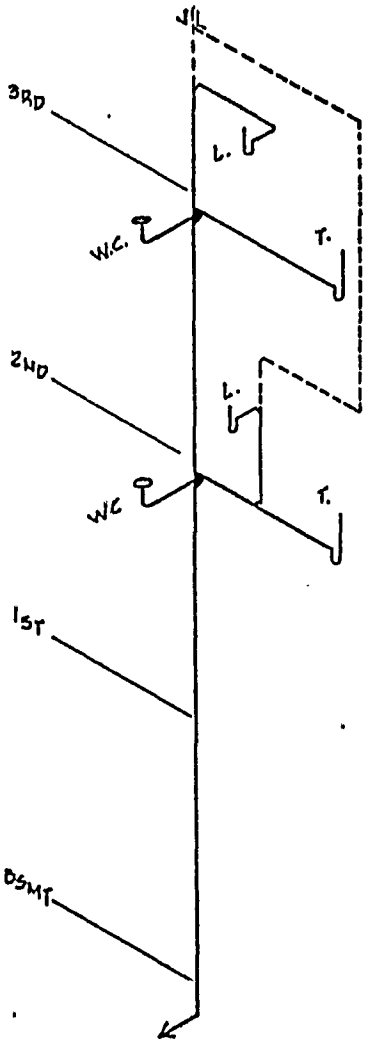


Figure 11

ADDITION OF SECOND OR THIRD FLOOR BATHROOM GROUP TO EXISTING 3-STORY STACK

For possible use of single stack solutions see 1.3(4) and discussion under 2.3.

Note that for addition of new water closet, tub, and lavatory to either second or third floor, second floor may be wet vented and third floor stack vented.

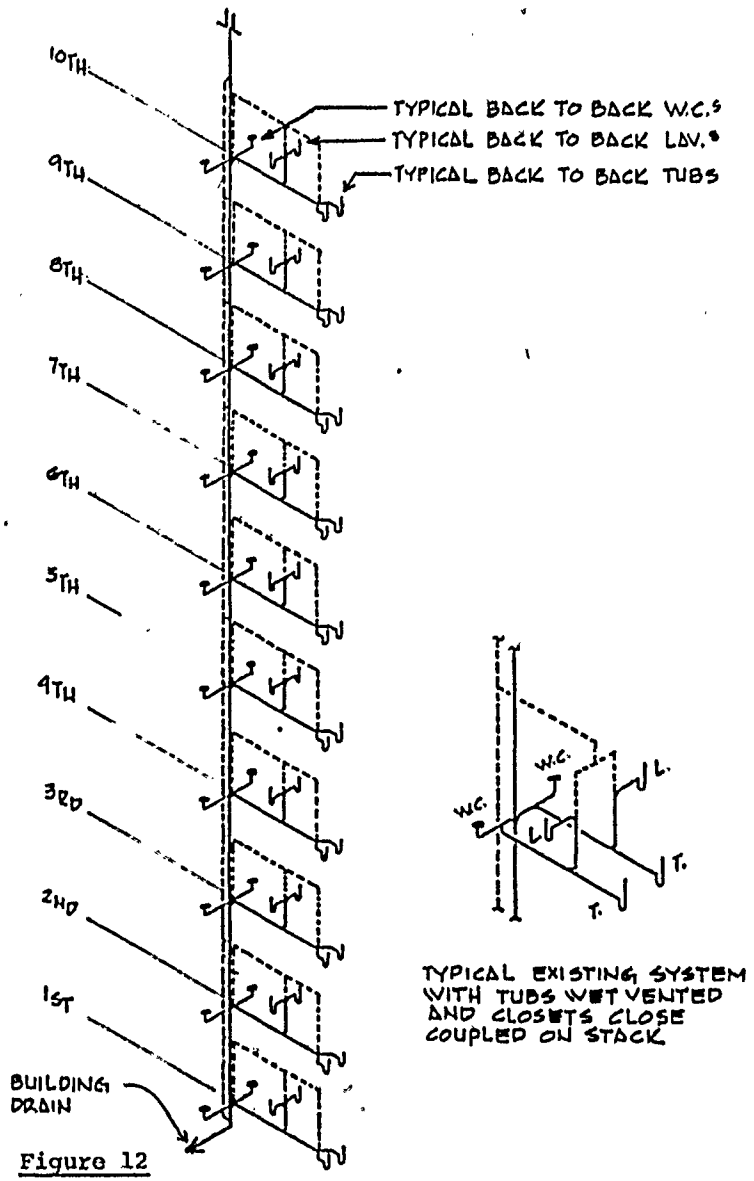


Figure 12

TYPICAL FULLY VENTED BACK-TO-BACK BATHROOM STACK WITH ALTERNATE SOLUTION

Illustration of use of wet venting in solving a problem of the type discussed under 2.3.

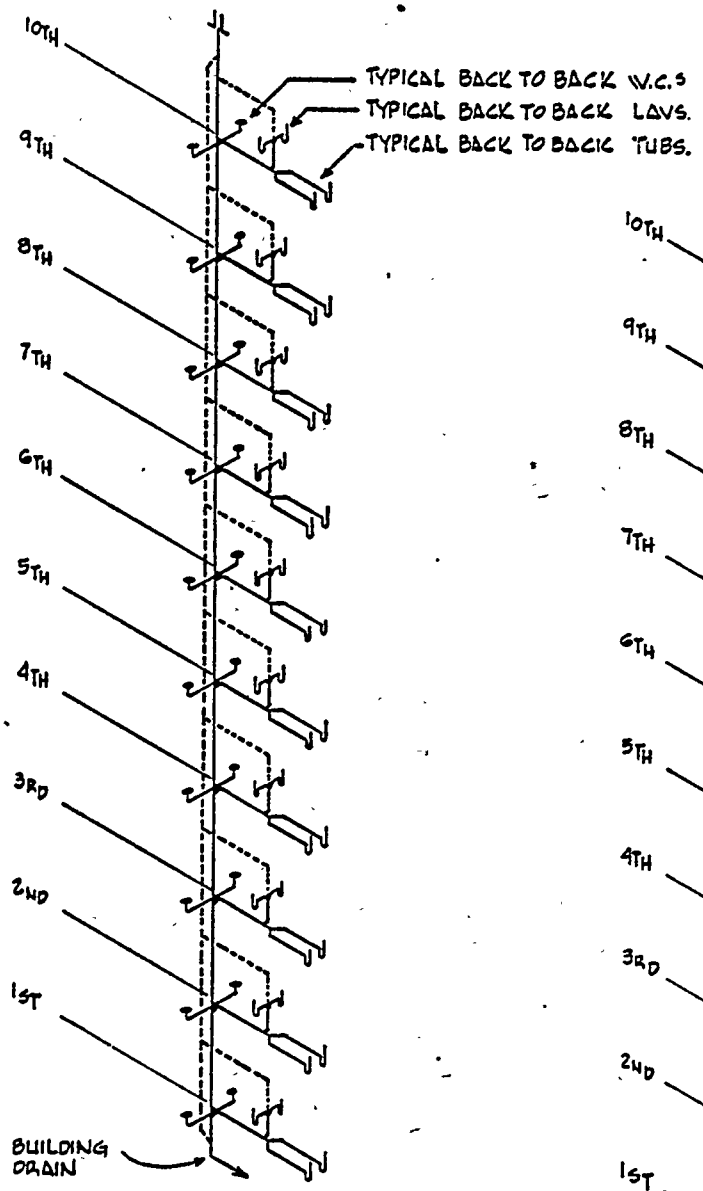


Figure 13

WET VENTING OF TUBS AND WATER CLOSETS

Illustration of possible solution to problem of the type discussed under 2.3.

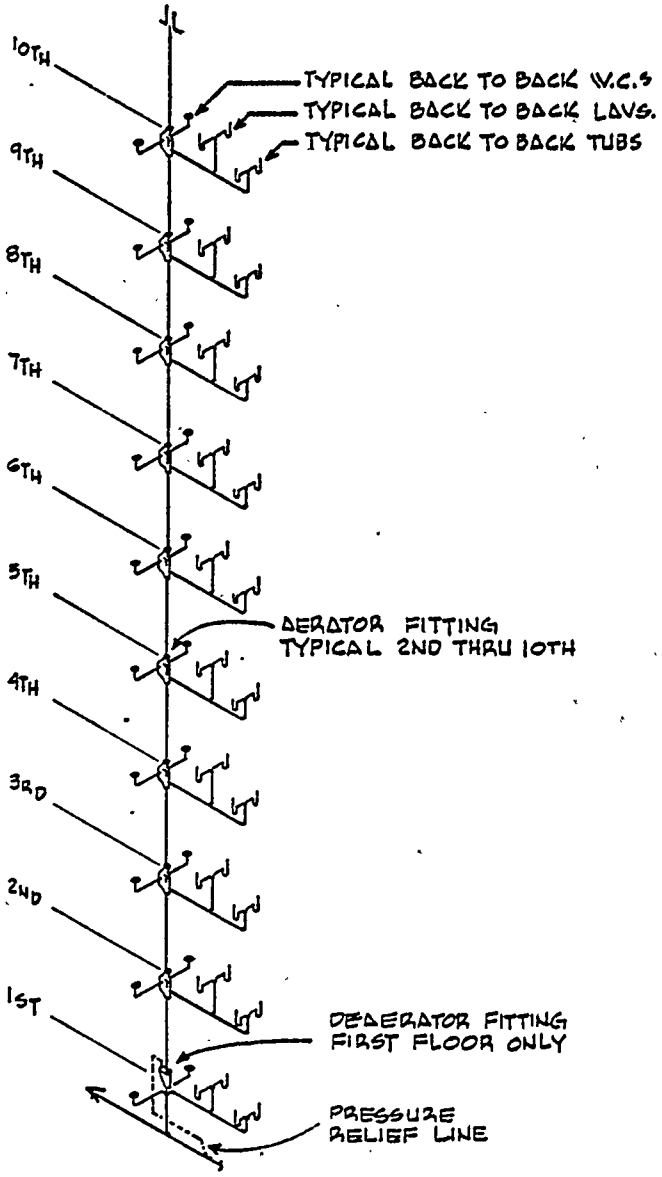


Figure 14

ENGINEERED SINGLE STACK SYSTEM SIZED ACCORDING TO PUBLISHED CRITERIA

Illustration of possible solution to problem of the type discussed under 2.3.

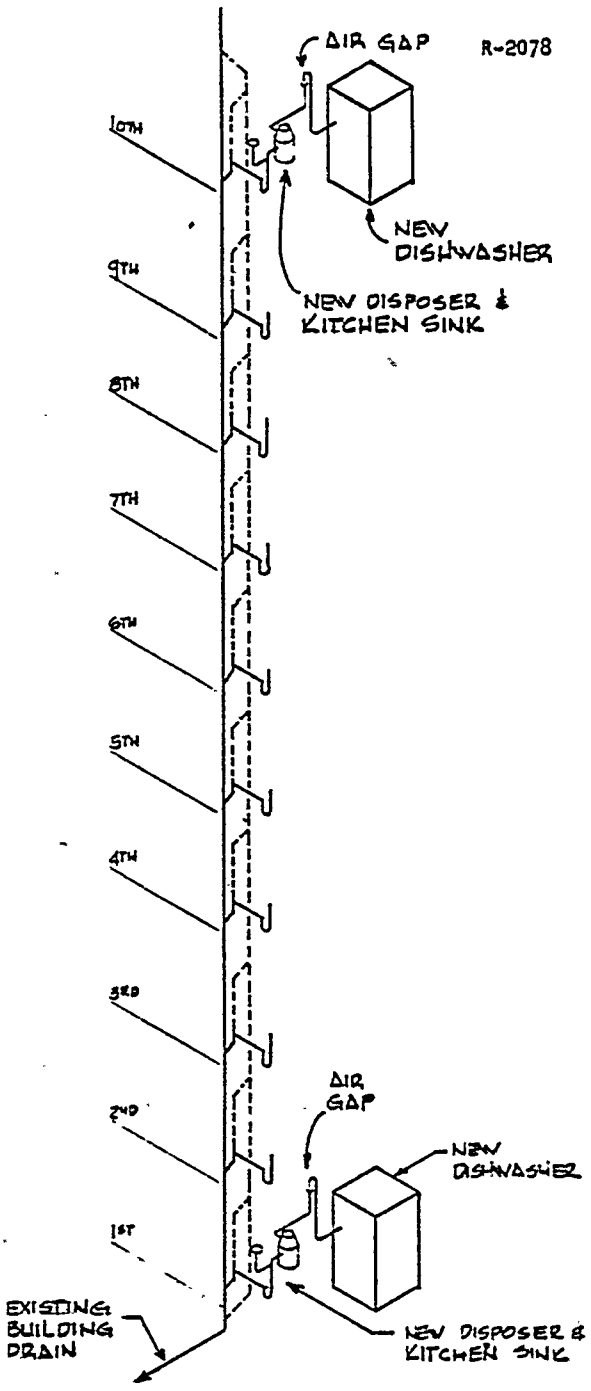


Figure 15

ADDITION OF DISPOSER AND DISHWASHER TO KITCHEN SINK ON EXISTING STACK

Illustration of acceptable addition of disposer and dishwasher to a 2 inch stack on every floor (see problem 2.3).

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Guideline on Fire Ratings of Archaic Materials and Assemblies

Table of Contents

Introduction

The *Guideline on Fire Ratings of Archaic Materials and Assemblies* focuses upon the fire-related performance of archaic construction. "Archaic" encompasses construction typical of an earlier time, generally prior to 1950. "Fire-related performance" includes fire resistance, flame spread, smoke production and degree of combustibility.

The purpose of this guideline is to update the information which was available at the time of original construction, for use by architects, engineers, and code officials when evaluating the fire safety of a rehabilitation project. The local manufacturing of many archaic materials means that there may never have been any fire test information available about the particular material of a given project. Information relevant to the evaluation of general classes of materials and types of construction is presented for these cases.

It has been assumed that the building materials and their fastening, joining, and incorporation into the building structue are sound mechanically. Therefore, some determination must be made that the original manufacture, the original construction practice, and the rigors of aging and use have not weakened the building. This assessment can often be difficult because process and quality control was not good in many industries, and variations among locally available raw materials and manufacturing techniques often resulted in a product which varied widely in its strength and durability. The properties of iron and steel, for example, varied widely, depending on the mill and the process used.

There is nothing inherently inferior about archaic materials or construction techniques. The pressures that promote fundamental change are most often economic or technological—matters not necessarily related to concerns for safety. The high cost of labor made wood lath and plaster uneconomical. The high cost of land and the congestion of the cities provided the impetus for high-rise construction. Improved technology made it possible. The difficulty with archaic materials is not a question of suitability, but familiarity.

Code requirements for the fire performance of key building elements (e.g., walls, floor/ceiling assemblies, doors, shaft enclosures) are stated in performance terms: hours of fire resistance. It matters not whether these elements were built in 1908 or 1980, only that they provide the required degree of fire resistance. This level of performance will be defined by the local community. The guideline is only a tool to help evaluate the various building elements, regardless of what the level of performance is required to be.

The problem with archaic materials is simply that documentation of their fire performance is not readily available. The application of engineering judgment is more difficult because building officials may not be familiar with the materials or construction method involved. As a result, either a fullscale fire test is required or the archaic construction in question removed and replaced. Both alternative are time consuming and wasteful.

This guideline and the accompanying Appendix are designed to help fill this information void. By providing the necessary documentation, there will be a firm basis for the continued acceptance of archaic materials and assemblies.

Section I Fire-Related Performance of Archaic Materials and Assemblies

A. Fire Performance Measures

This guideline does not specify the level of performance required for the various building components. These requirements are controlled by the building occupancy and use and are set forth in the local building or rehabilitation code.

The fire resistance of a given building element is established by subjecting a sample of the assembly to a "standard" fire test which follows a "standard" time temperature curve. This test method has changed little since the 1920's. The test results tabulated in the Appendix have been adjusted to reflect current test methods.

The current model building codes cite other fire-related properties not always tested for in earlier years: flame spread, smoke production, and degree of combustibility. However, they can generally be assumed to fall within well defined values because the principal combustible component of archaic materials is cellulose. Smoke production is more important today because of the increased use of plastics. However, the early flame spread tests, developed in the early 1940's, also included a test for smoke production.

"Plastics", one of the most important classes of contemporary materials, were not found in the review of archaic materials. If plastics are to be used in a rehabilitated building, they should be evaluated by contemporary standards. Information and documentation of their fire-related properties and performance is widely available.

Flame spread, smoke production and degree of combustibility are discussed in detail below. Test results for eight common species of lumber are noted in the following table:

Tunnel Test Results for Eight Species of Lumber (104)

Species of lumber	Flame spread	Fuel contributed	Smoke developed
Western white pine75 50–60 50			50
Northern white pine	120–215	120–140	60–65
Ponderosa pine	180–215	120–135	100–110
Yellow pine	180–190	130–145	275–305
Red gum	140–155	125–175	40–60
Yellow birch	105–110	100–105	45–65
Douglas fir	65–100	50–80	10–100
Western hemlock	60–75	40–65	40–120

Flame Spread

The flame spread of interior finishes is usually measured by the ASTM E–84 "tunnel test". The most commonly used flame spread classsifications (FSC) are: Class I or A,[1] with a 0–25 FSC; Class II or B, with a 26–75 FSC; and Class III or C, with a 76–200 FSC. The NFPA Life Safety Code also has a Class D (201–500 FSC) and Class E (over 500 FSC) interior finish. These classifications are typically used in modern building codes to restrict the rate of fire spread. Only the first three classifications are normally permitted, though not all classes of

[1] Some codes use Roman numerals, others use letters.

materials can be used in all places throughout a building. For example, the interior finish of building materials used in exits or in corridors leading to exits is more strictly regulated than materials used within private dwelling units.

In general, inorganic archaic materials (e.g., bricks or tile) can be expected to be in Class I. Materials of whole wood are mostly Class II. Whole wood is defined as wood used in the same form as sawn from the tree. This is in contrast to the contemporary reconstituted wood products such as plywood, fiberboard, hardboard or particle board. If the organic archaic material is not whole wood, the flame spread classification could be well over 200 and thus would be particularly unsuited for use in exits and other critical locations in a building. Some plywoods and various wood fiberboards have flame spreads over 200. Although they can be treated with fire retardants to reduce their flame spread, it would be advisable to assume that all such products have a flame spread over 200 unless there is information to the contrary.

Smoke Production

The evaluation of smoke density is part of the ASTM E-84 tunnel test. For the eight species of lumber shown in the table above, the highest levels are 275–305 for Yellow Pine, but the others are less smoky than red oak which has an index of 100. The advent of plastics caused substantial increases in the smoke density values measured by the tunnel test. The ensuing limitation of the smoke production for wall and ceiling materials by the model building codes has been a reaction to the introduction of plastic materials. In general, cellulosic materials fall in the 50–300 range of smoke density which is below the general limitation of 450 adopted by many codes.

Degree of Combustibility

There has been a tendency by the model building codes to define "noncombustibility" on the basis of having passed ASTM E-136 or if the material is totally inorganic. The acceptance of gypsum wallboard as noncombustible is based on limiting paper thickness to not over ⅛" and 0–50 flame spread classification (FSC) by ASTM E-84. At times there were provisions to define a Class I or A material (0–25 FSC) as noncombustible, but this is not currently recognized by most model building codes.

If there is any doubt whether or not an archaic material is noncombustible, it would be appropriate to send out samples for evaluation. If an archaic material is determined to be noncombustible according to ASTM E-136, it can be expected that it will not contribute fuel to the fire.

B. Combustible Construction Types

One of the earliest forms of timber construction utilized exterior load-bearing masonry walls with columns and/or wooden walls supporting wooden beams and floors in the interior of the building. This form of construction, often called "mill" or "heavy timber" construction, has approximately 1-hour fire resistance. The exterior walls will generally contain the fire within the building.

As population pressure increased and more lumber became available, there was a switch from heavy timber to "balloon frame" construction. The balloon frame uses load-bearing exterior wooden walls which have long timbers often extending from foundation to roof. When longer lumber became scarce, another form of construction, "platform" framing, replaced the balloon framing. The difference between the two systems is significant because platform framing is automatically fire-blocked at every floor while balloon framing commonly has concealed spaces that extend unblocked from basement to attic. The architect, engineer, and code official must be alert to the details of construction and the ease with which fire can spread in concealed spaces.

Section II Building Evaluation

A given rehabilitation project will most likely go through several stages. The preliminary evaluation process involves the designer in surveying the prospective building. The fire resistance of existing building materials and construction systems are identified; potential problems are noted for closer study. The final evaluation phase includes: developing design solutions to upgrade the fire resistance of building elements, if necessary; the preparation of working drawings and specifications; and the securing of the necessary code approvals.

A. Preliminary Evaluation

A preliminary evaluation should firstly consist of a building survey to determine the existing materials, the general arrangement of the structure, the use of the occupied space, and the details of construction. The designer needs to know "what is there" before a decision can be reached about what to keep and what to remove in the rehabilitation process. This preliminary evaluation should be as detailed as necessary to make initial plans. The fire-related properties need to be determined from the applicable building code, and the materials and assemblies existing in the building then need to be evaluated for these properties. Two work sheets are introduced below to facilitate the preliminary evaluation.

There are two possible sources of information that are relevant to the preliminary evaluation: original building plans and the building code in effect at the time of construction. Plans may be on file with the local building department or in the offices of the original design professionals (e.g., architect, engineer) or their successors. If plans are available, the investigator should verify that the building was actually constructed as called for in the plans, as well as incorporate any later alterations or changes to the building. Earlier editions of the local building code should be on file with the building official. The code in effect at the time of construction will contain fire performance criteria. While this is no guarantee that the required performance was actually provided, it does give the investigator some guidance as to the level of performance which may be expected. Under some code administration and enforcement systems, the code in effect at the time of construction also defines the level of performance that must be provided at the time of rehabilitation.

Table A is a suggested work sheet for the preliminary field notes. This work sheet lists the materials, thickness, and condition for each of the principal building elements. In addition to Table A, the field investigator should prepare a schematic diagram showing the exit system for the building and to indicate where each element from Table A fits into the structure as a whole. Each floor of the structure should be visited and the information in Table A completed. In practice, there will often be identical materials and construction on each floor, but the exception to this rule may be of vital importance. A drawing should be prepared of each floor showing the layout of exits and hallways. The exact arrangement of interior walls within apartments is of secondary importance from a fire safety point of view and need not be shown on the drawings unless these walls are required by the building code to have a fire resistance rating.

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TABLE A

PRELIMINARY EVALUATION

FIELD NOTES

Building Element		Materials	Dimension	Condition	Notes
Exterior Bearing Walls					
Interior Bearing Walls					
Exterior Non-Bearing Walls					
Interior Non-Bearing Walls or Partitions:	A				
	B				
Structural Frame:	Columns				
	Beams				
	Other				
Floor/Ceiling Structural System Spanning					
Roofs					
Doors (including frame and hardware):					
a) Enclosed vertical exitway					
b) Enclosed horizontal exitway					
c) Other					

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The location of stairways and elevators should be clearly marked on the drawings. All exterior means of escape (e.g., fire escapes) should be identified.[2]

The following notes explain the entries in Table A:

(i) *Exterior Bearing Walls:* Many old buildings utilize heavily constructed walls to support the floor/ceiling assemblies at the exterior of the building. There may be columns and/or interior bearing walls within the structure, but these exterior walls are an important factor in assessing the fire safety of a building.

The field investigator should note how the floor/ceiling assemblies are supported at the exterior of the building. If columns are incorporated in the exterior walls, the walls may be considered non-bearing.

(ii) *Interior Bearing Walls:* It may be difficult to determine whether or not an interior wall is load bearing, but the field investigator should attempt to make this determination. At a later stage of the rehabilitation process, this question will need to be determined exactly. Nevertheless, the field notes should be as accurate as possible.

(iii) *Exterior Non-Bearing Walls:* The fire resistance of the exterior walls is important for two reasons. These walls (both bearing and non-bearing) are depended upon to: a) contain a fire *within* the building; or b) keep an exterior fire *outside* the building. It is therefore important to indicate on the drawings where any openings are located as well as the nature of all doors or shutters. The drawings should indicate the presence of wired glass, its thickness and framing, and identify the materials used for windows and door frames. The protection of openings adjacent to exterior means of escape (e.g., exterior stairs, fire escapes) is particularly important. The ground floor drawing should locate the building on the property and indicate the precise distances to adjacent buildings.

(iv) *Interior Non-Bearing Walls (Partitions):* A partition is a "wall that extends from floor to ceiling and subdivides space within any story of a building." (48) Table A has two categories (A & B) for Interior Non-Bearing Walls (Partitions) which can be used for different walls, such as hallway walls as compared to inter-apartment walls. Under some circumstances there may be only one type of wall construction; in others, three or more types of wall construction may occur.

The field investigator should be alert for differences in function as well as in materials and construction details. As with the layout in general, the details within apartments are not as important as the major exit passages and stairwells. The preliminary field investigation should attempt to determine the thickness of all walls. A term introduced below called "thickness design" will depend on an accurate (± ¼") determination. Even though this intial field survey is called "preliminary", the data generated should be as accurate and complete as possible.

The field investigator should note the exact location from which his or her observations are recorded. For instance, if a hole is found through a stairwell wall which allows a cataloguing of the construction details, the field investigation notes should reflect the location of the "find." At the prliminary stage it is not necessary to core every wall; the interior details of construction can usually be determined at some location.

(v) *Structural Frame:* There may or may not be a complete skeletal frame, but usually there are columns, beams, trusses, or other elements. The dimensions and spacing of the structural elements should be measured and indicated on the drawings. For instance, if there are ten inch square columns located on a thirty foot square grid throughout the building, this should be noted. The structural material and cover or protective materials should be identified wherever possible. The thickness of the cover materials should be determined to an accuracy of ±¼". As discussed above, the preliminary field survey usually relies on accidental openings in the cover materials rather than a systematic coring technique.

(vi) *Floor/Ceiling Structural Systems:* The span between supports should be measured. If possible, a sketch of the cross-section of the system should be made. If there is no location where accidental damage has opened the floor/ceiling construction to visual inspection, it is necessary to make such an opening. An evaluation of the fire resistance of a floor/ceiling assembly requires detailed knowledge of the materials and their arrangement. Special attention should be paid to the cover on structural steel elements and the condition of suspended ceilings and similar membranes.

(vii) *Roofs:* The preliminary field survey of roof systems will generally focus mainly on water-tightness. However, once it is apparent that the roof is sound for ordinary use and can be retained in the rehabilitated building, it becomes necessary to evaluate its fire characteristics. The field investigator must measure the thickness and identify the types of materials which have been used. The investigator should be aware that there may be several layers of roof materials.

(viii) *Doors:* The doors to stairways and hallways represent some of the most important fire elements to be considered within a building.

The various uses are clearly differentiated in Table A. This should aid the field investigator in making careful measurements of the thickness of door panels and in the determination of the type of core material within each type of door. The presence of a self-closure on a door should be noted and the general operation of the doors should be checked. The latch should engage and the door should fit tightly in the frame. The hinges shoud be in good condition. If glass is used in the doors, it should be identified as either plain glass or wired glass mounted in either a wood or steel frame.

(ix) *Materials:* The field investigator should be able to identify ordinary building materials. In situations where an unfamiliar material is found, a sample should be obtained. This sample should measure at least 10 cubic inches so that an ASTM E–136 fire test can be conducted to detemine if it is combustible.

(x) *Thickness:* The thickness of all materials should be measured accurately since, under certain circumstances, the fire resistance rating is very sensitive to the material thickness.

(xi) *Condition:* The method of attaching the various layers and facings to one another or to the supporting structural element should be noted under the appropriate building element in the table. The "secureness" of the attachment and the general condition of the layers and facings should be noted here. The condition of the element and the different layers of materials is important, but at the preliminary stage a subjective judgment is sufficient for this evaluation process.

(xii) *"Notes:* The "Notes" column can be used for many purposes, but it might be a good idea to make specific references to field notes and/or drawings to complement the table.

The next step in the preliminary evaluation is to identify the required fire resistance and flame spread for each of the building elements. These are normally established by the local building code. Then, the fire performance of the existing building elements is determined. A comparison of the required and available ratings

[2] Problems providing adequate exiting are discussed at length in the *Egress Guideline for Residential Rehabilitation.*

will highlight any deficiencies. Ways of either upgrading or replacing deficient construction can then be identified. A suggested work sheet for organizing this information is given below as Table B.

B. Fire Resistance of Existing Building Elements

The fire resistance of the existing building elements can be estimated from the tables and histograms contained in the Appendix. The Appendix is organized first by type of building element: walls, columns, floor/ceiling assemblies, beams, and doors. Within each building element, the tables are organized by type of construction (e.g., masonry, metal, wood frame), and then further divided by minimum dimensions or thickness of the building element.

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TABLE B

PRELIMINARY EVALUATION

WORKSHEET

Building Element	Required Fire Resistance	Required Flame Spread	Estimated Fire Resistance	Estimated Flame Spread	Possible Upgrade	Possible Equivalent Protection	Notes
Exterior Bearing Walls							
Interior Bearing Walls							
Exterior Non-Bearing Walls							
Interior Non-Bearing Walls or Partitions	A						
	B						
Structural Frame: Columns							
Beams							
Other							
Floor/Ceiling Structural System Spanning							
Roofs							
Doors (including frame and hardware): a) Enclosed vertical exitway							
b) Enclosed horizontal exitway							
c) Others							

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A histogram precedes every table that has 10 or more entries. The X-axis measures fire resistance in hours; the Y-axis shows the number of entries in that table having a given level of fire resistance. The histograms also contain the location of each element within that table for easy cross-referencing.

The histograms, because they are keyed to the tables, can speed the preliminary investigation. For example, Table 1.3.2, "Wood Frame Walls 4" to less than 6" thick", contains 96 entries. Rather than study each table entry, the histogram shows that every wall listed in that table has a fire resistance of less than 2 hours. If the building code required the wall to have a 2-hour rating, the designer, with a minimum of effort, is made aware of a problem that requires closer study.

Suppose the code had only required a wall of 1-hour fire resistance. The histogram shows far fewer complying elements (19) than non-complying ones (77). If the existing element is not one of the 19 complying entries, there is a strong possibility the existing element is deficient. The histograms can also be used in the converse situation. If the existing element is not one of the smaller number of entries with a lower than required fire resistance, there is a strong possibility the existing element will be acceptable.

At some point the existing building component must be actually located within the tables. Otherwise, the fire resistance must be determined through one of the techniques presented in Section III of the guideline. Locating the building component not only guarantees the accuracy of the fire resistance rating, but also provides a source of documentation for the building official.

C. Effects of Penetrations in Fire Resistant Assemblies

There are often many features in existing walls or floor/ceiling assemblies which were not included in the original certification or fire testing. The most common example is pipes and utility wires passed through holes poked through the assembly. During the life of the building, many penetrations are added and by the time a building is ready for rehabilitation, it is not sufficient to just consider the fire resistance of the assembly as originally constructed. It is necessary to consider all penetrations and their impact upon fire performance. For instance, the fire resistance of corridor walls is not as important as the effect of plain glass doors or transoms. In fact, doors are the most important single class of penetrations.

A fully developed fire generates substantial quantities of heat and excess fuel capable of penetrating any holes which might be present in the walls or ceiling of the fire compartment. In general, this leads to a severe degradation of the fire resistance of those elements and to a greater potential for fire spread. This is particularly applicable to penetrations located high in a compartment where the positive pressure of the fire can force the unburned gases through the penetration.

Penetrations in a floor/ceiling assembly will generally completely negate the barrier qualities of the assembly, and will lead to rapid spread of fire to the space above. It will not be a problem, however, if the penetrations are filled with noncombustible materials strongly fastened to the structure. The upper half of walls are similar to the floor/ceiling assembly in that a positive pressure can reasonably be expected in the top of the room, and this will push hot and/or burning gases through the penetration unless it is completely sealed.

Building codes require doors installed in fire resistive walls to resist the passage of fire for a specified period of time. If the door to a fully involved room is not closed, a large plume of fire will typically escape through the doorway, preventing anyone from using the space outside the door while allowing the fire to spread. This is why door closers are so important. Glass in doors and transoms can be expected to rapidly shatter unless constructed of listed or approved wire glass in a steel frame. As with other building components, penetrations or non-rated portions of doors and transoms must be upgraded or otherwise protected.

Table 5.1 in Section V of the Appendix contains 41 entries of doors mounted in sound tightfitting frames. Section III (D) below outlines one procedure for evaluating and possibly upgrading existing doors.

Section III Final Evaluation and Design Solutions

The final evaluation begins after the rehabilitation project has reached the final design stage and the choices made to keep certain archaic materials and assemblies in the rehabilitated building. The specific fire resistance and flame spread requirements are determined for the project. This may involve local building and fire officials reviewing the preliminary evaluation as depicted on Table A, Table B, and the field drawings and notes. The final evaluation process is essentially a more refined and detailed version of the preliminary evaluation. When necessary, provisions must be made to upgrade existing building components to provide the required level of fire resistance.

This section identifies specific approaches to design solutions that can make possible the continued use of archaic materials and assemblies in the rehabilitated structure. The simplest case occurs when the materials and assembly in question are found within the Appendix Tables and the fire performance properties satisfy code requirements. Other approaches must be used, though, if the assembly cannot be found within the Appendix or the fire performance needs to be upgraded. These approaches have been grouped into two classes: experimental and theoretical.

A. The Experimental Approach

If the fire resistance rating of a material and/or assembly found in a building is not given in the Appendix Tables of this report, there are several other ways to evaluate its fire performance. One approach is to conduct the appropriate fire test(s) and thereby determine the fire-related properties directly. There are a number of laboratories in the United States which routinely conduct the various fire tests. A current list can be obtained by writing the Center for Fire Research, National Bureau of Standards, Washington, D.C. 20234.

The contract with any of these testing laboratories should require their observation of specimen preparation as well as the testing of the specimen. A complete description of where and how the specimen was obtained from the building, the transportation of the specimen, and its preparation for testing should be noted in detail so that the building official can be satisfied that the fire test is representative of the actual use of the material in the building.

The test report should describe the fire test procedure and the response of the material or assembly. The laboratory usually submits a cover letter with the report to describe the provisions of the fire test that were satisfied by the material or assembly under investigation. A building official will generally require this cover letter, but will also read the report to confirm that the material or assembly complies with the code requirements. Local code officials should be involved in all phases of the testing process.

The experimental approach can be costly and time consuming because specimens must be taken from the building and transported to the testing laboratory. When a load bearing assembly has continuous reinforcement,

the test specimen must be removed from the building, transported, and tested in one piece. However, when the fire performance cannot be determined by other means, there may be no alternative to a full-scale test.

A "non-standard" small-scale test can be used in special cases. Sample sizes need only be 10–25 square feet, while full-scale tests require test samples of either 100 or 180 square feet in size. This small-scale test is best suited for testing non-load bearing assemblies against thermal transmission only.

B. The Theoretical Approach

There will be instances when certain materials and assemblies in a building undergoing rehabilitation cannot be found in the Appendix Tables. Even in those cases where test results are available for more or less similar construction, the proper classification may not be immediately apparent. Variations in dimensions, loading conditions, materials, or workmanship may markedly affect the performance of the individual building elements, and the extent of such a possible effect cannot be evaluated from the tables.

Theoretical methods being developed offer an alternative to the full-scale fire tests discussed above. For example, Section 4302(b) of the 1979 Edition of the Uniform Building Code specifically allows an engineering design for fire resistance in lieu of conducting full scale tests. These techniques draw upon computer simulation and mathematical modeling, thermodynamics, heat-flow analysis, and materials science to predict the fire performance of building materials and assemblies.

Another theoretical method known as the "Ten Rules of Fire Endurance Ratings" was published by T. Z. Harmathy in the May, 1965 edition of *Fire Technology*. (35) Using the data from the Appendix as a base, Harmathy's Rules provide a foundation for extending the data to analyze or upgrade current as well as archaic building materials or assemblies.

Harmathy's Ten Rules

Rule 1: The "thermal" [3] fire endurance of a construction consisting of a number of parallel layers is greater than the sum of the "thermal" fire endurances characteristic of the individual layers when exposed separately to fire.

(i) The minimum performance of an untested assembly can be estimated if the fire endurance of the individual components is known. Though the exact rating of the assembly cannot be stated, the endurance of the assembly is greater than the sum of the endurance of the components.

(ii) When a building assembly or component is found to be deficient, the fire endurance can be upgraded by providing a protective membrane. This membrane could be a new layer of brick, plaster, or drywall. The fire endurance of this membrane is called the "finish rating." Tables 1.5.1 and 1.5.2 contain the finish ratings for the most commonly employed materials. (See note (ii) to Rule 2).

(iii) The test criteria for the finish rating is the same as for the thermal fire endurance of the total assembly: average temperature increases of 250° F above ambient or 325° F above ambient at any one place with the membrane being exposed to the fire. The temperature is measured at the interface of the assembly and the protective membrane.

Rule 2: The fire endurance of a construction does not decrease with the addition of further layers.

(i) Harmathy notes that this rule is a consequence of the previous rule. Its validity also follows from the fact that, by the addition of further layers, both the resistance to heat flow and the heat capacity of the construction increase, which, in turn, reduce the rate of temperature rise at the unexposed surface.

(ii) This rule is not just restricted to "thermal" performance but affects the other fire test criteria: direct flame passage, cotton waste ignition, and load bearing performance. This means that certain restrictions must be imposed on the materials to be added and on the loading conditions. One restriction is that new layer, if applied to the exposed surface, must not produce additional thermal stresses in the construction, i.e., its thermal expansion characteristics must be similar to those of the adjacent layer. Each new layer must also be capable of contributing enough additional strength to the assembly to sustain the added dead load. If this requirement is not fulfilled, the allowable live load must be reduced by an amount equal to the weight of the new layer. Because of these limitations, this rule should not be applied without careful consideration of these restrictions.

(iii) Particular care must be taken if the material added is a good thermal insulator. Preperly located, the added insulation could improve the "thermal" performance of the assembly. Improperly located, the insulation could block necessary thermal transmission through the assembly, thereby subjecting the structural elements to greater temperatures for longer periods of time, and could cause premature structural failure of the supporting members.

Rule 3: The fire endurance of constructions containing continuous air gaps or cavities is greater than the fire endurance of similar constructions of the same weight, but contining no air gaps or cavities.

(ii) By providing for voids in a construction, additional resistances are produced in the path of heat flow. Numerical heat flow analyses indicate that a 10 to 15 percent increase in fire endurance can be achieved by creating an air gap at the mid-plane of a brick wall. Since the gross volume is also increased by the presence of voids, the air gaps and cavities have a beneficial effect on stability as well. However, constructions containing combustible materials within an air gap may be regarded as exceptions to this rule because of the possible development of burning in the gap.

(ii) There are numerous examples of this rule in the tables. For instance:

Table 1.1.4; Item W–8–M–82: Cored concrete masonry, nominal 8" thick wall with *one unit* in wall thickness and with 62 percent minimum of solid material in each unit, load bearing (80 PSI). *Fire endurance is 2½ hours.*

Table 1.1.5; Item W–10–M–11: Cored concrete masonry, nominal 10" thick wall with *two units* in wall thickness and a 2" *air space,* load bearing (80 PSI). The units are essentially the same as item W–8–M–82. *Fire endurance is 3½ hours.*

These walls show 1-hour greater fire endurance by the addition of the 2" air space.

Rule 4: The farther an air gap or cavity is located from the exposed surface, the more beneficial is its effect on the fire endurance.

(i) Radiation dominates the heat transfer across an air gap or cavity, and it is markedly higher where the temperature is higher. The air gap or cavity is thus a poor insulator if it is located in a region which attains high temperatures during fire exposure.

(ii) Some of the clay tile designs take advantage of these factors. The double cell design, for instance, insures that there is a cavity near the unexposed face. Some floor/ceiling assemblies have air gaps or cavities near the top surface and these enhance their thermal performance.

Rule 5: The fire endurance of a construction cannot be increased by

[3] The "thermal" fire endurance is the time at which the average temperature on the unexposed side of a construction exceeds its initial value by 250° F when the other side is exposed to the "standard" fire specified by ASTM Test Method E-119.

increasing the thickness of a completely enclosed air layer.

(i) Harmathy notes that there is evidence that if the thickness of the air layer is larger than about ½ inch, the heat transfer through the air layer depends only on the temperature of the bounding surfaces, and is practically independent of the distance between them. This rule is not applicable if the air layer is not completely enclosed, i.e., if there is a possibility of fresh air entering the gap at an appreciable rate.

Rule 6: Layers of materials of low thermal conductivity are better utilized on that side of the construction on which fire is more likely to happen.

(i) As in Rule 4, the reason lies in the heat transfer process, but here the conductivity of the solid is much less dependent on the ambient temperature. The low thermal conductor allows a substantial temperature gradient to be established across its thickness under transient heat flow conditions. This rule may not be applicable to materials undergoing physico-chemical changes accompanied by significant heat absorption or heat evolution.

Rule 7: The fire endurance of asymmetrical constructions depends on the direction of heat flow.

(i) This rule is a consequence of Rules 4 and 6 as well as other factors. This rule is useful in determining the relative protection of corridors and stairwells from the surrounding spaces. In addition, there are often situations where a fire is more likely, or potentially more severe, from one side or the other.

Rule 8: The presence of moisture, if it does not result in explosive spalling, increases the fire endurance.

(i) The flow of heat into an assembly is greatly hindered by the release and evaporation of the moisture found within cementitious materials such as gypsum, portland cement, or magnesium oxychloride. Harmathy has shown that the gain in fire endurance may be as high as 8 percent for each percent (by volume) of moisture in the construction. It is the moisture chemically bound within the construction material at the time of manufacture or processing that leads to increased fire endurance. There is not direct relationship between the relative humidity of the air in the pores of the material and the increase in fire endurance.

(ii) Under certain conditions there may be explosive spalling of low permeability cementitious materials such as dense concrete. In general, one can assume that extremely old concrete has developed enough minor cracking that this factor should not be significant.

Rule 9: Load-supporting elements, such as beams, girders and joists, yield higher fire endurances when subjected to fire endurance tests as parts of floor, roof, or ceiling assemblies than they would when tested separately.

(i) One of the fire endurance test criteria is the ability of a load-supporting element to carry its design load. The element will be deemed to have failed when the load can no longer be supported.

(ii) Failure usually results for two reasons. Some materials, particularly steel and other metals, lose much of their structural strength at elevated temperatures. Physical deflection of the supporting element, due to decreased strength or thermal expansion, causes a redistribution of the load forces and stresses throughout the element. Structural failure often results because the supporting element is not designed to carry the redistributed load.

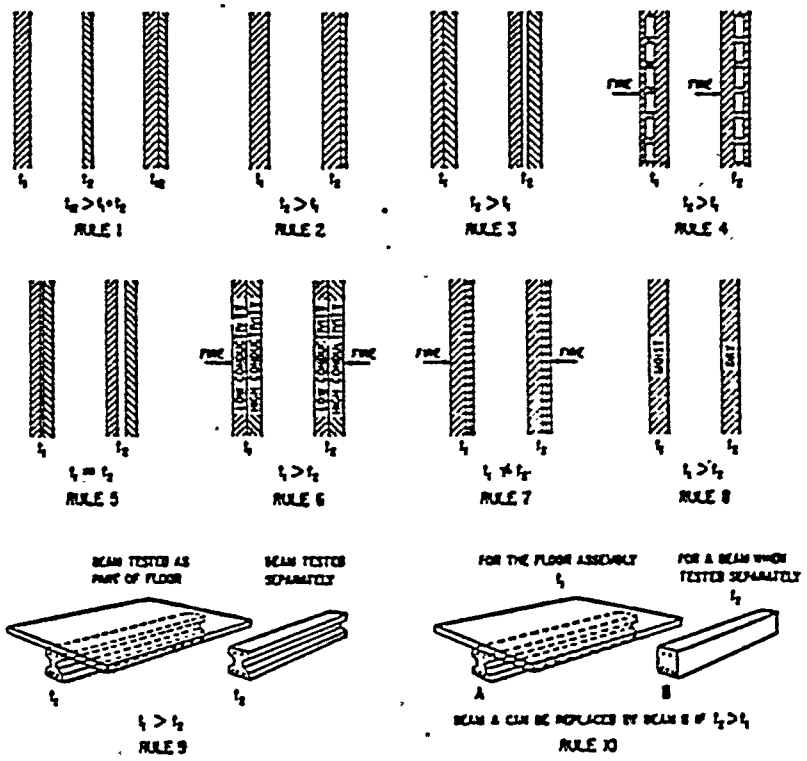
(iii) Roof, floor, and ceiling assemblies have primary (e.g., beams) and secondary (e.g., floor joists) structural members. Since the primary load-supporting elements span the largest distances, their deflection becomes significant at a stage when the strength of the secondary members (including the roof or floor surface) is hardly affected by the heat. As the secondary members follow the deflection of the primary load-supporting element, an increasingly larger portion of the load is transferred to the secondary members.

When load-supporting elements are tested separately, the imposed load is constant and equal to the design load throughout the test. By definition, no distribution of the load is possible because the element is being tested by itself. Without any other structural members to which the load could be transferred, the individual elements cannot yield a higher fire endurance than they do when tested as parts of a floor, roof or ceiling assembly.

Rule 10: The load-supporting elements (beams, girders, joists, etc.) of a floor, roof, or ceiling assembly can be replaced by such other load-supporting elements which, when tested separately, yielded fire endurances not less than that of the assembly.

(i) This rule depends on Rule 9 for its validity. A beam or girder, if capable of yielding a certain performance when tested separately, will yield an equally good or better performance when it forms a part of a floor, roof or ceiling assembly. It must be emphasized that the supporting element of one assembly must not be replaced by the supporting element of another assembly if the performance of this latter element is not known from a separate (beam) test. Because of the load-reducing effect of the secondary elements that results from a test performed on an assembly, the performance of the supporting element alone cannot be evaluated by simple arithmetic. This rule also indicates the advantage of performing separate fire tests on primary load-supporting elements.

Harmathy (35) provided one schematic figure which illustrated his Rules. This is shown below.* It should be useful as a quick reference to assist in applying his Rules.



Diagrammatic illustration of ten rules.

t = fire endurance

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Example Applications of Harmathy's Rules

The following examples, based in whole or in part upon those presented in Harmathy's paper (35), show how the Rules can be applied to practical cases.

Example 1

A. *Problem*

(i) A contractor would like to keep a partition which consists of a 3¾ inch thick layer of red clay brick, a 1¼ inch thick layer of plywood and a ⅜ inch thick layer of gypsum wallboard, at a location where 2-hour fire endurance is required. Is this assembly capable of providing a 2-hour protection?

B. *Solution*

(i) This partition does not appear in the Appendix Tables.

(ii) Bricks of this thickness yield fire endurances of approximately 75 minutes (Table 1.1.2, Item W–4–M–2).

(iii) The 1¼ inch thick plywood has a finish rating of 30 minutes. (iv) The ⅜ inch gypsum wallboard has a finish rating of 10 minutes.

(v) Using the recommended values from the Tables and applying Rule 1, the

fire endurance of the assembly is larger than the sum of the layers, or

>75+30+10=115 minutes

C. *Discussion*

(i) This example illustrates how the Appendix Tables can be utilized to determine the fire resistance of assemblies not explicitly listed.

Example 2

A. *Problem*

(i) A number of buildings to be rehabilitated have the same type of roof slab which is supported with different structural elements.

(ii) The designer and contractor would like to determine whether or not this roof slab is capable of yielding a 2-hour fire endurance. According to a rigorous interpretation of ASTM E-119, however, only the roof assembly, including the roof slab as well as the cover and the supporting elements, can be subjected to a fire test. Therefore, a fire endurance classification cannot be issued for the slab separately.

(iii) The designer and contractor believe this slab will yield a 2-hour fire endurance even without the cover, and any beam of at least 2-hour fire endurance may serve as satisfactory support. Is it possible to obtain a classification for the slab separately?

B. *Solution*

(i) The answer to the question is yes.

(ii) According to Rule 10 it is not contrary to common sense to test and classify roofs and supporting elements separately. Furthermore, according to Rule 2, if the roof slabs actually yield a 2-hour fire endurance, the endurance of an assembly, including the slabs, cannot be less than two hours.

(iii) The recommended procedure would be to review the tables to see if the slab appears as part of any tested roof or floor/ceiling assembly. The supporting system can be regarded as separate from the slab specimen, and the fire endurance of the assembly listed in the table is at least the fire endurance of the slab. There would have to be an adjustment for the weight of the roof cover in the allowable load if the test specimen did not contain a cover.

(iv) The supporting structure or element would have to have at least a 2-hour fire endurance when tested separately.

C. *Discussion*

If the tables did not include tests on assemblies which contained the slab, one procedure would be to assemble the roof slabs on any convenient supporting system (not regarded as part of the specimen) and to subject them to a load which, besides the usually required superimposed load, includes some allowances for the weight of the cover.

Example 3

A. *Problem*

(i) A steel-joisted floor and ceiling assembly is known to have yielded a fire endurance of 1 hour and 35 minutes. At a certain location, a 2-hour fire endurance is required. What is the most economical way of increasing the fire endurance by at least 25 minutes?

B. *Solution*

(i) The most effective technique would be to increase the ceiling plaster thickness. Existing coats of paint would have to be removed and the surface properly prepared before the new plaster could be applied. Other materials (e.g., gypsum wallboard) could also be considered.

(ii) There may be another technique based on other principles, but an examination of the drawings would be necessary.

C. *Discussion*

(i) The additional plaster has at least three effects:

a) The layer of plaster is increased and thus there is a gain of fire endurance (Rule 1).

b) There is a gain due to shifting the air gap farther from the exposed surface (Rule 4).

c) There is more moisture in the path of heat flow to the structural elements (Rules 7 and 8).

(ii) The increase in fire endurance would be at least as large as that of the finish rating for the added thickness of plaster. The combined effects in (i) above would further increase this by a factor of 2 or more, depending upon the geometry of the assembly.

Example 4

A. *Problem*

(i) The fire endurance of item W-10-M-1 in Table 1.1.5 is 4-hours.This wall consists of two 3¾ inch thick layers of structural tiles separated by a 2-inch air gap and ¾" Portland cement plaster or stucco on both sides. If the actual wall in the building is identical to item W-120-M-1 except that it has a 4-inch air gap, can the fire endurance be estimated at 5 hour-

B. *Solution*

(i) The answer to the question is no.

(ii) Reason contained in Rule 5.

Example 5

A. *Problem*

(i) In order to increase the insulating value of its precast roof slabs, a company has decided to make the slabs using two layers of different concretes. The lower layer of the slabs, where the strength of the concrete is immaterial (all the tensile load is carried by the steel reinforcement), is now made from a concrete of low strength but good insulating value, For the upper layer, where the concrete is supposed to carry the compressive load, the original high strength, high thermal conductivity concrete has been retained, How will the fire endurance of the slabs be affected by the changes?

B. *Solution*

The effect on the thermal fire endurance is beneficial:

(i) The total resistance to heat flow of the new slabs has been increased due to the replacement of a layer of high thermal conductivity by one of low conductivity.

(ii) The layer of low conductivity is on the side more likely to be exposed to fire, where it is more effectively utilized according to Rule 6. The layer of low thermal conductivity also provides better protection for the steel reinforcement, thereby extending the time before reaching the temperature at which the creep of steel becomes significant.

C. "Thickness Design" Strategy

If a given wall does not appear in the tables, a rehabilitation designer can utilize a "thickness design" strategy for walls which is based on Harmathy's Rules 1 and 2.

This "thickness design" approach is used when the materials have been identified and measured, but the specific wall is not included in the tables. The first step is to survey thinner walls to see if the same materials have been fire tested and if thinner walls have yielded the desired or greater fire endurance. If that is the case, then the thicker walls in the building have more than enough fire resistance. The thickness of the walls thus becomes the principal concern.

This approach can also be used for floor/ceiling assemblies, except that the thickness of the cover [4] and the slab become the central concern. The fire resistance of the untested assembly will be at least the fire resistance of an assembly listed in the table having a similar design but with less cover and/or thinner slabs. For other structural elements (e.g., beams and columns), the element listed in the table must be of a similar design but with less cover thickness.

D. Evaluation of Doors

A separate section on doors has been included because the process for evaluation presented below differs from those suggested previously for other building elements. The impact of

[4] Cover: The protective layer of membrane of material which slows the flow of heat to the structural elements.

unprotected openings or penetrations in fire resistant assemblies has been detailed in Section II (C) above. It is sufficient to note here that openings left unprotected will likely lead to failure of the barrier under actual fire conditions.

For other types of building elements (e.g., beams, columns), the Appendix Tables can be used to establish a minimum level of fire performance. The benefit to rehabilitation is that the need for a full-scale fire test is then eliminated. For doors, however, this cannot be done. The data contained in Appendix Table 5.1, "Resistance of Doors to Fire Exposure", can only provide guidance as to whether a successful fire test is even feasible.

For example, a door required to have 1-hour fire resistance is noted in the tables as providing only 5 minutes. The likelihood of achieving the required 1-hour, even if the door is upgraded, is remote. The ultimate need for replacement of the doors is reasonably clear, and the expense and time needed for testing can be saved. However, if the performance documented in the table is near or in excess of what is being required, then a fire test should be conducted. The test documentation can then be used as evidence of compliance with the required level of performance.

The table entries cannot be used as the sole proof of performance of the door in question because there are too many unknown variables which could measurably affect fire performance. The wood may have dried over the years; coats of flammable varnish could have been added. Minor deviations in the internal construction of a door can result in significant differences in performance. Methods of securing inserts in panel doors can vary. The major non-destructive method of analysis, an x-ray, often cannot provide the necessary detail. It is for these, and similar reasons, that a fire test is still felt to be necessary.

It is often possible to upgrade the fire performance of an existing door. Sometimes "as is" and modified doors are evaluated in a single series of tests when failure of the unmodified door is expected. Because doors upgraded after an initial failure must be tested again, there is a potential savings of time and money.

The most common problems encountered are plain glass, panel inserts of insufficient thickness, and improper fit of a door in its frame. The latter problem can be significant because a fire can develop a substantial positive pressure, and the fire will work its way through otherwise innocent-looking gaps between door and frame.

One approach to solving these problems is as follows. The plain glass is replaced with approved or listed wire glass in a steel frame. The panel inserts can be upgraded by adding an additional layer of material. Gypsum wallboard is often used for this purpose. Intumescent paint applied to the edges of the door and frame will expand when exposed to fire, forming an effective seal around the edges. This seal, coupled with the generally even thermal expansion of a wood door in a wood frame, can prevent the passage of flames and other fire gases. The figure below illustrates these solutions.

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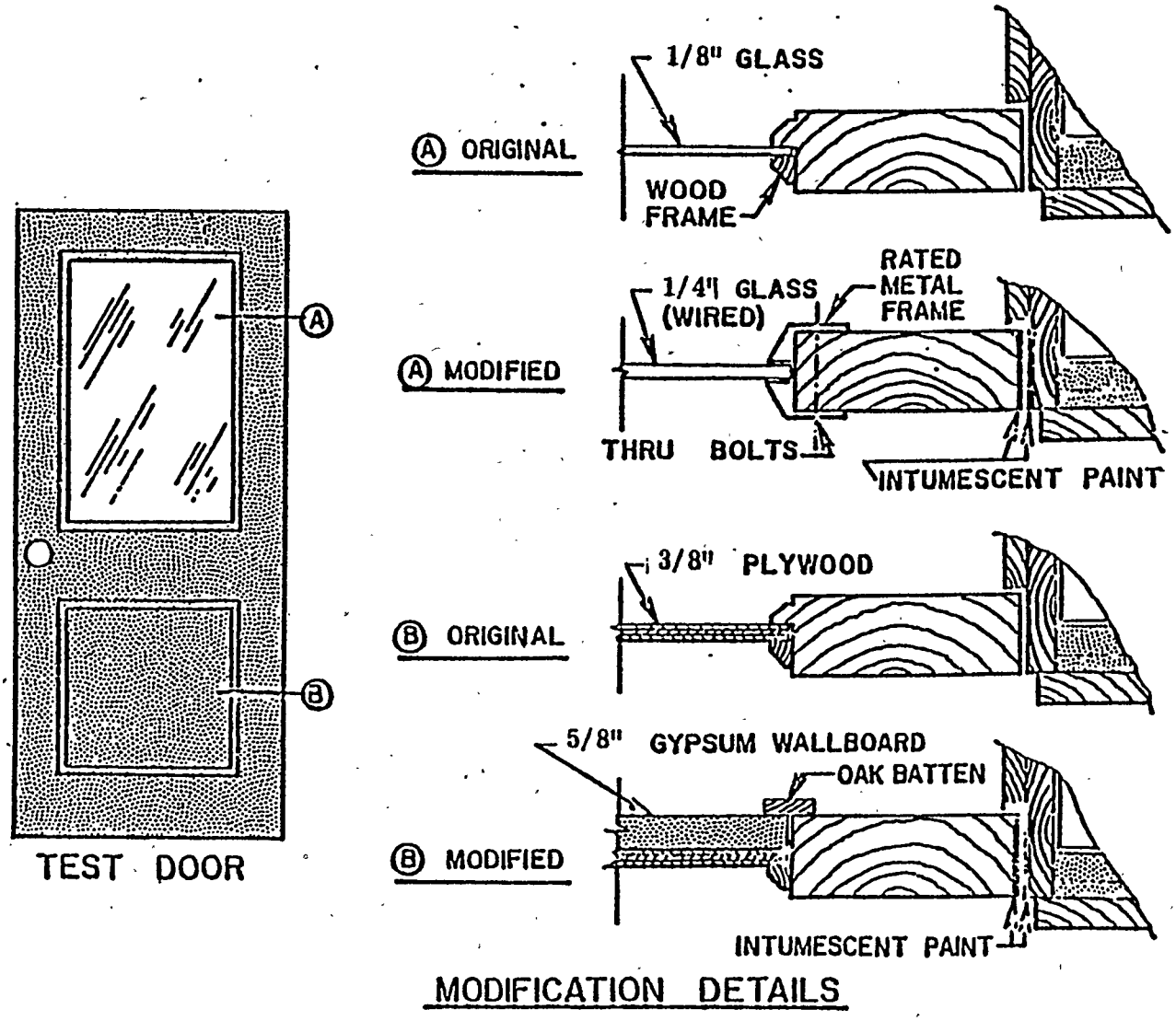

MODIFICATION DETAILS

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Because the interior construction of a door cannot be determined by a visual inspection, there is no absolute guarantee that the remaining doors are identical to the one(s) removed from the building and tested. But the same is true for doors constructed today, and reason and judgment must be applied. Doors that appear identical upon visual inspection can be weighed. If the weights are reasonably close, the doors can be assumed to be identical and therefore provide the same level of fire performance. Another approach is to fire test more than one door or to dismantle doors selected at random to see if they had been constructed in the same manner. Original building plans showing door details or other records showing that doors were purchased at one time or obtained from a single supplier can also be evidence of similar construction.

More often though, it is what is visible to the eye that is most significant. The investigator should carefully check the condition and fit of the door and frame, for frames out of plumb or separating from the wall. Door closers, latches, and hinges must be examined to see that they function properly and are tightly secured. If these are in order and the door and frame have passed a full-scale test, there can be a reasonable basis for allowing the existing doors to remain.

Section IV Summary Guideline

After the preliminary evaluation has been documented and a rehabilitation project is in the final design process, the need arises for specific guidelines for the evaluation of the fire-related performance of existing building elements. This section summarizes the various approaches and design solutions discussed in the preceeding Sections.

The term "structural system" includes: frames, beams, columns, and other structural elements. "Cover" has the meaning defined below: a protective layer(s) of materials or membrane which slows the flow of heat to the structural elements.

The following approaches (i) through (iii) shall be considered equivalent.

(i) The fire resistance of a building element can be established from the Appendix Tables. This is subject to the following limitations:

a. The building element in the rehabilitated building shall be constructed of the same materials with the same nominal dimensions as stated in the tables.

b. All penetrations in the building element or its cover for services such as electricity, plumbing, and HVAC shall be packed with noncombustible cementitious materials and so fixed that the packing material will not fall out when it loses its water of hydration.

c. The effects of age and wear and tear shall be repaired so that the building element is sound and the original thickness of all components, particularly covers and floor slabs, is maintained.

(ii) The fire resistance of a building element which does not explicitly appear in the Appendix Tables can be established if one or more elements of same design but different dimensions have been listed in the tables. For walls, the existing element must be thicker than the one listed. The fire resistance of the thicker wall shall be considered that of the thinner wall which appears in the table. For floor/ceiling assemblies, the assembly listed in the table must have the same or less cover and the same or thinner slab constructed of the same material as the actual floor/ceiling assembly. For other structural elements, the element listed in the table must be of a similar design but with less cover thickness. The fire resistance in all instances shall be the fire resistance rating recommended in the table. This is subject to the following limitations:

a. The actual element in the rehabilitated building shall be constructed of the same materials as listed in the table. Only the following dimensions may vary from those specified: for walls, the overall thickness must exceed that specified in the table; for floor/ceiling assemblies, the thickness of the cover and the slab must be greater than, or equal to, that specified in the table; for other structural elements, the thickness of the cover must be greater than that specified in the table.

b. All penetrations in the building element or its cover for services such as electricity, plumbing, or HVAC shall be packed with noncombustible cementitious materials and so fixed that the packing material will not fall out when it loses its water of hydration.

c. The effects of age and wear and tear shall be repaired so that the building element is sound and the original thickness of all components, particularly covers and floor slabs, is maintained.

(iii) The fire resistance of building elements can be established by applying Harmathy's Ten Rules of Fire Resistance Ratings as set forth in Section III (B). This is subject to the following limitations:

a. The data from the Tables can be utilized with the limitations a. through c. from Guideline (i) above.

(b) Test reports from recognized journals or published papers can be used to support data utilized in applying Harmathy's Rules.

c. Calculations utilizing recognized and well established computational techniques can be used in applying Harmathy's Rules. These include, but are not limited to, analysis of heat flow, mechanical properties, deflections, and load bearing capacity.

Commentary

(i) Guideline (i) essentially follows the approach taken by model building codes. The assembly must appear in a table either published in or accepted by the code for a given fire resistance rating to be recognized and accepted.

(ii) Guideline (ii) is an application of the "thickness design" concept presented in Section III (C). There should be many instances when a thicker building element was utilized than the one listed in the Appendix Tables. This Guideline recognizes the inherent superiority of a thicker design. Note: "thickness design" for floor/ceiling assemblies and structural elements refers to cover and slab thickness rather than total thickness.

(iii) The "thickness design" concept is essentially a special case of Guideline (iii) which takes special cognizance of Harmathy's Rules (specifically Rules 1 and 2). It should be recognized that the only source of data for Guideline (ii) is the Appendix Tables. If other data are used, it must be in connection with Guideline (iii).

(iv) The fire endurance of actual building elements can be greatly reduced or totally negated by removing part of the cover to allow pipes, ducts, or conduits to pass through the element. This must be repaired in the rehabilitation process.

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May 27, 1980

Part IV

Department of Energy

Privacy Act; Records Maintained on Individuals

DEPARTMENT OF ENERGY

10 CFR Part 1008

Privacy Act; Records Maintained on Individuals

AGENCY: Department of Energy.

ACTION: Proposed regulations.

SUMMARY: These regulations propose the procedures to be followed and the substantive principles to be applied by the Department of Energy (DOE) in implementing its responsibilities under the Privacy Act of 1974, 5 U.S.C. 552a (Privacy Act). The regulations set forth the procedures under which individuals may seek access to their records and request correction of those records. The regulations also set forth employee standards of conduct with regard to personal records within the scope of the Privacy Act. Additionally, there are provisions pertaining to the dissemination of records of parties other than the requesting individual and provisions applicable to the Department's establishment and maintenance of systems of records. These regulations are also applicable to contractors and their employees to the extent required by 5 U.S.C. 552a(m).

COMMENT DATE: June 26, 1980.

ADDRESS: Interested persons are invited to submit written comments with respect to the proposed guidelines to: Kenneth E. Cohen, Acting Assistant General Counsel for Legal Counsel, Room 6H–058, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252–8618.

FOR FURTHER INFORMATION CONTACT:

Leslie Borden Greenspan, Office of General Counsel, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252–8618.

Milton Jordan, Office of Administrative Services, Room 5B–138, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 252–5955.

SUPPLEMENTARY INFORMATION:

I. Background

The DOE was established by the Department of Energy Organization Act (Pub. L. 95–91) (the Act), which became effective on October 1, 1977 pursuant to Executive Order 12009, dated September 13, 1977 (42 FR 46267, September 15, 1977). The Act transfers to and vests in the DOE the functions of the former Federal Energy Administration, the Energy Research and Development Administration, and specified functions of several other agencies, including the Department of Interior. These regulations represent a consolidation, with some procedural adaptation, of the Privacy Act regulations previously followed by the Federal Energy Administration and the Energy Research and Development Administration, two of the major components of the new Department. The regulations apply to all Privacy Act matters pertaining to the Department, except that they do not apply to the Federal Energy Regulatory Commission (FERC), an independent collegial body within DOE.

II. Discussion

These regulations establish a procedure that geographically decentralizes the administration of the DOE's program for implementing the Privacy Act of 1974 to various DOE field locations and appropriate Privacy Act Officers, to be designated by the Director, Office of Administration. Each Privacy Act Officer will be responsible for the following: (i) Advising all DOE personnel of the provisions, including the criminal penalties and civil liabilities of the Privacy Act and of their responsibilities thereunder and (ii) the initial processing of requests, including verifying the identity of individuals making request for access to or correction of records and identifying the System Manager or Managers within the Department that maintain the records which are the subject of such requests.

Each Privacy Act Officer will make decisions pertaining to the validity of requests under these regulations, coordinate the collection of records from the System Manager or Managers, and be responsible for preparing responses granting or denying requests. Indentification, collection and review of records to determine whether to grant access or to correct a record are within the responsibility and authority of the System Manager, and Managers maintaining the records who, after reviewing the material shall transmit a recommended decision to the Privacy Act Officer; consultation with the concurrence of DOE General Counsel is required.

Appeals of initial decisions, whether from the Headquarters or any field office, will continue to be directed only to the DOE, Office of Hearings and Appeals.

The administrative appeal procedures in section 1008.11 of these regulations are applicable only to denials of requests for records maintained by DOE on its own behalf. They do not apply to the government-wide systems that have been reported by the Office of Personnel Management (OPM), but are in the custody of DOE. Appeals of denials of access and amendment of these records are governed by OPM regulations 5 CFR Part 297 published at (44 FR 65031, November 9, 1979), and are to be directed to the Assistant Director for Agency Compliance and Evaluations, OPM.

The Privacy Act defines certain substantive parameters within which Federal agencies administer their Privacy Act programs. These substantive provisions (pertaining, for example, to the types of records which may be maintained by an agency, the accounting of disclosures, the exemption of certain information from disclosure, and the exemptions permitting disclosure to third parties) are reflected in these regulations, and in most practical respects represent a consolidation of parallel provisions appearing in the regulations of the Department's predecessor agencies. The regulations, however, include additional guidance pertaining to several aspects of the Privacy Act program. First, although the Privacy Act does not specifically require it, the regulations provide for an administrative appeal from initial denials of access to requested records. Second, although there are no time limits in the Privacy Act for the processing of requests or appeals, the regulations set forth time periods in this regard. The processing of initial requests for access shall be accomplished promptly, with every effort being made to respond within ten working days of the date of receipt. Actions on initial requests for correction or amendment and all actions on appeal are to be taken within 20 working days of receipt of the request. These provisions make the time periods for the processing of Privacy Act actions consistent with those required by statute for the processing of requests and appeals under the Freedom of Information Act. Moreover, the regulations also make it clear that the Freedom of Information Act exemptions shall not be invoked to limit an individual's access to records pertaining to him to which he is entitled under the Privacy Act.

Section 1008.12(a)(2) exempts, under subsection (j)(2) of the Privacy Act, the Inspector General's investigative files. Under subsection (j)(2), an agency or agency component whose principal function is "any activity pertaining to the enforcement of criminal laws * * *," may exempt systems of records which include information compiled for

criminal investigation from many provisions of the Privacy Act.

The Inspector General's investigative files may be exempted under subsection (j)(2) exemption because the principal function of the Office of the Inspector General is—

"to supervise, coordinate, and provide policy direction for auditing and investigative activities relating to the promotion of economy and efficiency in the administration of, or the prevention or detection of fraud or abuse in, programs and operations of the Department * * *." (Section 208(b), DOE Organization Act, Pub. L. No. 95-91.)

These records are compiled by the Inspector General in the course of criminal investigations.

The system would be exempted from the following requirements: to provide individual access to and amendment of records and accounting for disclosures; to collect information where possible from the subject individual; to inform the individual of the authority, purpose, and uses to be made of the information and of the disclosure of records under compulsory legal process; and to describe the individual access and amendment procedures. The system would also be exempted from the standards of accuracy and relevance.

III. Revocations

These regulations, when adopted, will supersede the Privacy Act regulations for the Energy Research and Development Administration (10 CFR Part 708) and the Federal Energy Administration (10 CFR Part 206). At the time these regulations become final, the above-cited regulations of the predecessor agencies of the DOE will be revoked.

IV. Other Procedural Considerations

In accordance with Council on Environmental Quality regulations (40 CFR Parts 1500-1508) for implementing the procedural provisions of the National Environmental Policy Act, no Environmental Assessment or Environmental Impact Statement is necessary for the publication of these proposed regulations since these regulations do not affect the quality of the environment.

In accordance with section 501(c)(1) of the Department of Energy Organization Act, DOE has determine that these regulations present no substantial issue of fact or law, and are unlikely to have a substantial impact on the economy or large numbers of individuals or businesses. Accordingly, no public hearing is required.

The DOE has also determined that this document is not a significant regulation requiring preparation of a regulatory analysis under Executive Order 12044, as implemented by DOE Order 2030.1, since the anticipated effects of the proposal, if made final, would be primarily to provide internal guidance for the implementation of the Privacy Act.

Interested persons are invited to submit written comments with respect to the proposed guidelines to: Kenneth E. Cohen, Acting Assistant General Counsel for Legal Counsel, Room 6H-058, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252-8618.

Comments should be identified on the outside envelope and on documents submitted to DOE with the designated Privacy Act Regulations. Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing. The DOE reserves the right to determine the confidential status of the information or data and to treat it according to its determination. Comments should be provided on or before June 26, 1980.

(Department of Energy Organization Act, Pub. L. 95-91, Executive Order 12091, 42 FR 46267, Privacy Act of 1974, Pub. L. 93-579 (5 U.S.C. 552a))

In consideration of the foregoing, it is proposed that the regulations set forth below be adopted.

Issued in Washington, D.C., on May 16, 1980.

Charles W. Duncan, Jr.,
Secretary.

PART 1008—RECORDS MAINTAINED ON INDIVIDUALS (PRIVACY ACT)

Subpart A—General Provisions

Sec.

Subpart B—Requests for Access or Amendment

Subpart C—Disclosure to Third Parties

Subpart D—Maintenance and Establishment of Systems of Records

Authority: (Department of Energy Organization Act, Pub. L. 95-91, Executive Order 12091, 42 FR 46267, Privacy Act of 1974, Pub. L. 93-579 (5 U.S.C. 552a)).

Subpart A—General Provisions

§ 1008.1 Purpose and scope.

(a) This part establishes the procedures to implement the Privacy Act of 1974 (Pub. L. 93-579, 5 U.S.C. 552a.) within the Department of Energy.

(b) This part applies to all systems of records, as defined in § 1008.2(m), maintained by DOE.

(c) This part applies to all divisions within the DOE, and to the personnel records of the Federal Energy Regulatory Commission (FERC), which are maintained by DOE on behalf of FERC. These regulations do not apply to other systems of records maintained by FERC. These regulations also apply to DOE contractors and their employees to the extent required by 5 U.S.C. 552a(m).

§ 1008.2 Definitions

(a) "Department" or "Department of Energy (DOE)" means all organizational entities which are a part of the executive department created by Title II of the Department of Energy Organization Act, Pub. L. 95-91, except the Federal Energy Regulatory Commission (FERC).

(b) "Director, Office of Hearings and Appeals" means the Director or his delegate.

(c) "DOE locations" means each of the following DOE components:

(1) Alaska Power Administration, P.O. Box 50, Juneau, AK 88801.

(2) Albuquerque Operations Office, P.O. Box 5400, Albuquerque, NM 87115.

Note.—This office has cognizance over the following area offices: Amarillo, Dayton, Kansas City, Los Alamos, Pinellas, Rocky Flats and Sanria.

(3) Bartlesville Energy Technology Center, P.O. Box 1398, Bartlesville, OK 74003.

(4) Bonneville Power Administration, P.O. Box 3621, Portland, OR 97268.
(5) Chicago Operations Office, 9800 South Cass Avenue, Argonne, IL 60439.

Note.—This office has cognizance over the Batvia and Brookhaven area offices and the New Brunswick laboratory.

(6) Grand Forks Energy Technology Center, P.O. Box 8213, University Station, Grand Forks, ND 58201.
(7) Grand Junction Office, P.O. Box 2567, Grand Junction, CO 81502.
(8) Headquarters, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.
(9) Idaho Operations Office, 550 2nd Street, Idaho Falls, ID 83401
(10) Laramie Energy Technology Center, P.O. Box 3395, University Station, Laramie, WY 82070.
(11) Morgantown Energy Technology Center, P.O. Box 880, Morgantown, WV 26505.
(12) Nevada Operations Office, P.O. Box 14100, Las Vegas, NV 89114
(13) Oak Ridge Operations Office, P.O. Box E, Oak Ridge, TN 37830.
(14) Oak Ridge Technical Information Center, P.O. Box 62, Oak Ridge, TN 37830.
(15) Pittsburgh Energy Technology Center, 4800 Forbes Avenue, Pittsburgh, PA 15213.
(16) Region I: Analex Building, Room 700, 150 Causeway Street, Boston, MA 02114.
(17) Region II: 26 Federal Plaza, Room 3206, New York, NY 10007.
(18) Region III: 1421 Cherry Street, 10th Floor, Philadelphia, PA 19102.
(19) Region IV: 1655 Peachtree Street, NE, 8th Floor, Atlanta, GA 30309.
(20) Region V: 175 West Jackson Boulevard, Room A-333, Chicago, IL 60604.
(21) Region VI: P.O. Box 35228, 2626 West Mockingbird Lane, Dallas, TX 75235.
(22) Region VII: Twelve Grand Building, 1150 Grand Avenue, Kansas City, MO 64106.
(23) Region VIII: P.O. Box 26247—Belmar Branch, 1075 South Yukon Street, Lakewood, CO 80226.
(24) Region IX: 111 Pine Street, Third Floor, San Francisco, CA 94111.
(25) Region X: 1992 Federal Building, 915 Second Avenue, Seattle, WA 98174.
(26) Richland Operations Office, P.O. Box 550, Richland, WA 99352.
(27) San Francisco Operations Office, 1333 Broadway, Wells Fargo Building, Oakland, CA 94612.
(28) Savannah River Operations Office, P.O. Box "A" Aiken, SC 29801.
(29) Southeastern Power Administration, Elberton, GA 30635.
(30) Southwestern Power Administration, P.O. Drawer 619, Tulsa, OK 74101.
(31) Western Area Power Administration, P.O. Box 3402, Golden, CO 80401.

(d) "General Counsel" means the General Counsel provided for in section 202(b) of the Department of Energy Organization Act, or any DOE attorney designated by the General Counsel.

(e) "Headquarters" means all DOE facilities functioning within the Washington, D.C. metropolitan area.

(f) "Individual" means a citizen of the United States or an alien lawfully admitted for permanent residence, but does not include proprietorships, businesses, or corporations. Where appropriate, the term "individual" also includes a duly authorized representative of an individual.

(g) "Maintain" means maintain, collect, use, or disseminate.

(h) "Privacy Act Officer" means the person designated by the Director, Office of Administration, as responsible for administering the DOE's program for implementing the requirements of the Privacy Act of 1974 at the DOE locations listed at § 1008.2(c).

(i) "Record" means any item, collection, or grouping of information about an individual that is maintained by or for the DOE including, but not limited to, education, financial transactions, medical history, and criminal or employment history, and that contains that individual's name, or other identifying number, symbol, or other identifying particulars assigned to the individual, such as a finger or voice print or photograph.

(j) "Routine use" means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected.

(k) "Statistical record" means a record in a system of records maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual, except as provided by 13 U.S.C. section 8.

(l) "System Manager" means the DOE official who is responsible for a system of records as designated in the system notice of that system of records published by DOE.

(m) "System of records" means a group of any records under DOE control from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particulars assigned to the individual.

§ 1008.3 Employee standards of conduct with regard to privacy.

(a) The Headquarters DOE Privacy Act Officer shall assure that DOE personnel are advised of the provisions of the Privacy Act, including the criminal penalties and civil liabilities provided therein, and that DOE personnel are made aware of their responsibilities: To protect the security of personal information to assure its accuracy, relevance, timeliness and completeness; to avoid unauthorized disclosure; and to insure that no system of records concerning individuals, no matter how insignificant or specialized, is maintained without public notice.

(b) DOE personnel shall:

(1) Collect or maintain no information of a personal nature about individuals unless relevant and necessary to achieve a purpose or carry out a responsibility of the DOE as required by statute or by executive order.

(2) Collect information, wherever possible, directly from the individual to whom it pertains.

(3) Inform individuals from whom information is collected of the authority for collection, the principal purposes for which the information will be used, the routine uses that will be made of the information, and the effects of not furnishing the information.

(4) Collect, maintain, use or disseminate no information concerning an individual's rights guaranteed by the First Amendment, unless (i) the individual has volunteered such; or (ii) the information is expressly authorized by statute to be collected, maintained, used or disseminated; or (iii) the activities involved are pertinent to and within the scope of an authorized law enforcement activity.

(5) Advise their supervisors of the existence or proposal of any system of records which retrieves information about individuals by the individual's name or other identifying number, symbol, or identifying particulars assigned to the individual.

(6) Maintain an accounting, in the prescribed form, of all disclosures of information other than those to officers or employees who have a need for the record in the performance of their duties and those required under the Freedom of Information Act.

(7) Disclose no records other than to DOE personnel, except when authorized by 5 U.S.C. 552a or pursuant to a routine use published in the Federal Register.

(8) Maintain and process information concerning individuals with care to insure that no inadvertent disclosure of the information is made.

(9) Inform the proper DOE authorities of any information maintained in a DOE

system of records which is not authorized by the Privacy Act of 1974.

(c) Heads of Headquarters Divisions and Offices and heads of the other DOE locations shall review annually the systems of records subject to their responsibility to insure compliance with the requirements of the Privacy Act of 1974.

§ 1008.4 Procedures for identifying the individual making a request for access to or amendment of records.

(a) When a request for information about or for access to or correction of a record pertaining to an individual and contained in a system of records has been made pursuant to § 1008.6 valid identification of the individual making the request shall be required before information will be given, access be granted or a correction considered, to insure that information is given, corrected, or records disclosed or corrected only at the request of the proper person.

(b) Subject to paragraphs (c) and (d) of this section, an individual making a request may establish his identity by:

(1) Including with his request, if submitted by mail, a photocopy of two identifying documents bearing his name and signature, one of which shall bear his current home or business address and date of birth; or

(2) Appearing at the appropriate DOE location during the regular business hours and presenting either of the following:

(i) One identifying document bearing the individual's photograph and signature, such as a driver's license or passport; or

(ii) Two identifying documents bearing the individual's name and signature, one of which shall bear the individual's current home or business address and date of birth; or

(3) Providing such other proof of identity as the Privacy Act Officer deems satisfactory in the circumstances of a particular request.

(c) If the Privacy Act Officer or the appropriate System Manager determines that the information in a record is so sensitive that unauthorized access could cause harm or embarrassment to the individual whose record is involved, or if the individual making the request is unable to produce satisfactory evidence of identity under paragraph (b) or (d) of this section, the individual making the request may be required to submit a notarized statement attesting to his identity and his understanding of the criminal penalties provided under section 1001 of Title 18 of the United States Code for making false statements to a Government agency and under section 552a(i)(3) of the Act for obtaining records under false pretenses. Copies of these statutory provisions and forms of such notarized statements may be obtained upon request from the Privacy Act Officer, Headquarters, Department of Energy, Washington, D.C.

(d) When an individual acting as the parent of a minor or the legal guardian of the person to whom a record pertains makes a request pursuant to § 1008.6 of this part—

(1) Such an individual shall establish his personal identity in the same manner required in either paragraphs (b) or (c) of this section.

(2) In addition, such an individual shall establish his identity in the representative capacity of parent or legal guardian. In the case of the parent of a minor, the proof of identity shall be a certified or authenticated copy of the minor's birth certificate. In the case of the legal guardian of a person who has been declared incompentent due to physical or mental incapacity or age by a court of competent jurisdiction, the proof of identity shall be a certified or authenticated copy of the order from a court of competent jurisdiction.

(3) A parent or legal guardian may act only for a living individual, not for a decedent.

§ 1008.5 Effect of the Freedom of Information Act (FOIA).

(a) DOE shall not rely on any exemption contained in the Freedom of Information Act (5 U.S.C. 552) to withhold from the individual to whom it pertains, any record which is otherwise accessible to such individual under this part.

(b) DOE shall rely on section (b) of the Privacy Act to withhold information from a person other than the person to whom the record pertains only when the information is also exempt from disclosure under the FOIA.

(c) Where a request for access to records is submitted pursuant to both the FOIA and the Privacy Act, the DOE shall, to the maximum extent possible, process the request under the provisions of this part, including the timing requirements of this part.

Subpart B—Requests for Access or Amendment

§ 1008.6. Procedures for requesting information about or for access to or correction or amendment of an individual's own records in a system of records.

(a) Any individual may request information regarding whether a system of records maintained by the DOE contains any information pertaining to him, and may request access to this information. Any individual may also request the correction or amendment of information pertaining to him that is contained in a system of records. Requests may be made by mail or in person during DOE's regular business hours and shall be directed to the Privacy Act Officer at the appropriate DOE location at the address listed in § 1008.2(c).

(b) Requests submitted pursuant to this section shall comply with the following provisions:

(1) The request, whether by mail or in person, shall be in writing and signed by the individual making the request. It should state that this request is a "Privacy Act Access" or a "Privacy Act Amendment" request and shall include any information required by § 1008.4 to be submitted for identification purposes.

(2) In addition, the request should:

(i) Specify the title and identifying number of the system of records which appears in the notice of systems of records published in the Federal Register by the DOE or its predecessor agencies, as appropriate.

(ii) Provide additional identifying information (consistent with the terms of the system notice) which may assist DOE in responding to the request; and

(iii) Describe the information sought and the time, place, or form of access, as appropriate.

(3) A request for correction or amendment of a record may be made by any individual if the requester believes that it is not accurate, relevant, timely, or complete. Amendment requests may include inquiries concerning—

(i) Whether such information is relevant or necessary to accomplish a purpose that DOE is required to accomplish by statute or by executive order of the President; or

(ii) If the information is to be used by DOE in making a determination about the individual, whether the requester believes such information is as accurate, relevant, timely or complete as is reasonably necessary to assure fairness in the determination.

(4) A request for correction or amendment of a record should include the elements listed in subparagraphs (2) (i) and (ii) of this paragraph. The request shall also specify the nature of the amendment sought, including the specific words to be deleted or added and shall present justification for the requested change, including any available supporting documents. The statement of justification for the change should identify the basis for the request (i.e., whether the information in the record is believed to be unnecessary, inaccurate, irrelevant, untimely or incomplete).

(c) Any request not addressed and marked as specified in paragraph (a) of this section shall be forwarded immediately to the appropriate Privacy Act Officer. An improperly addressed request will not be deemed to have been received for purposes of measuring time periods pursuant to §§ 1008.7 and 1008.10 until actual receipt by the appropriate Privacy Act Officer. The individual making the request shall be notified that the request was improperly addressed and the date when the request was received by the Privacy Act Officer.

(d) Assistance in preparing an access request pursuant to this section may be obtained from any DOE Privacy Act Officer at the locations listed at § 1008.2(e).

(e) An individual shall not be required to state a reason or otherwise justify his request for information, access to, or correction of a record pertaining to him/her that is contained in a system of records.

§ 1008.7 Processing of requests.

(a) Receipt of a request made in accordance with § 1008.6 of this part shall be promptly acknowledged by the Privacy Act Officer.

(b) Each request shall be acted upon promptly. Every effort will be made to respond within ten working days of the date of receipt by the System Manager or designee. If a response cannot be made within ten working days, the appropriate Privacy Act Officer shall send an interim response providing information on the status of the request, including an estimate of the time within which action is expected to be taken on the request and asking for any further information as may be necessary to respond to the request. Action will be completed as soon as possible, but not later than 20 working days after receipt of the original specific inquiry. In unusual circumstances and for good cause, the appropriate Privacy Act Officer may decide that action cannot be completed within the initial 20 working days. In such case, the appropriate Privacy Act Officer will advise the individual of the reason for the delay and the date (not to exceed an additional 20 working days) by which action can be expected to be completed.

(c) The term "unusual circumstances" as used in this section includes situations where a search for requested records from inactive storage is necessary; cases where a voluminous amount of data is involved; instances where information on other individuals must be separated or expunged from the particular record; and cases where consultation with other agencies which have substantial interest in the response to the request is necessary.

(d) Upon receiving a request, the Privacy Act Officer shall ascertain which System Manager or Managers of the DOE have primary responsibility for, custody of, or concern with the system of systems of records subject to the request and shall forward the request to such System Manager or Managers. The System Manager or Managers shall promptly identify and, in consultation with the General Counsel, review the records encompassed by the request.

(e) Where a request files pursuant to § 1008.6 involves records in the files of the DOE that have been obtained from other Federal agencies or that contain information obtained from other Federal agencies, the Privacy Act Officer shall do the following:

(1) Where an entire record originated in another agency, refer the request to the originating agency, and inform the requesting party of the appropriate official with whom to pursue his request.

(2) Where a DOE record contains information received from another agency, coordinate with the responsible official of the other agency. Such coordination will be conducted on an expedited basis, for the purposes of determining whether the other agency official wishes to deny the request and of obtaining the certification, signature, and identity of the other agency's responsible official. The notice of determination to the requesting party, in the event part or all of the record is denied by the other agency, shall cite the other agency's responsible official, as well as the appropriate DOE official if a denial by DOE is also involved.

(f) Where the request is for access to or information about records, after reviewing the material the System Manager or Mangers concerned shall transmit to the Privacy Act Officer the requested material. The transmission to the Privacy Act Officer shall include any recommendation that the request be granted or wholly or partially denied and shall set forth any exemption categories supporting denials. Any denial recommendation must be concurred in by the appropriate General Counsel.

(g) Where the request is for correction or amendment or records, after reviewing the material the System Manager or Managers shall transmit a recommended decision to the Privacy Act Officer. Any recommendation that the request be granted or wholly or partialliy denied shall set forth the policy considerations and any statutory basis supporting denials. Any recommendation of denial must be concurred in by General Counsel.

§ 1008.8 Action in response to a request for access: Disclosure of requested information to subject individuals.

(a) Consistent with the recommendation of the System Manager and the concurrence of the appropriate General Counsel, the Privacy Act Officer shall provide to the requesting individual the information about or access to a record or information pertaining to the individual contained in a system of records, unless the request is being denied in accordance with § 1008.9. The Privacy Act Officer shall notify the individual of such determination and provide the following information:

(1) Whether there is information of a record pertaining to him that is contained in a system of records;

(2) The methods of access as set-forth in paragraph (b) of this section;

(3) The place at which the record or information may be inspected;

(4) The earliest date on which the record or information may be inspected and the period of time that the record or information will remain available for inspection. In no event shall the earliest date be later than thirty calendar days from the date of notification.

(5) An indication that copies of the records are enclosed, or the estimated date by which a copy of the record could be mailed and the estimate of fees that would be charged to provide other than the first copy of the record, pursuant to § 1008.13.

(6) The fact that the individual, if he wishes, may be accompanied by another person during the in-person review of the record or information, provided that the individual shall first furnish to the Privacy Act Officer a written statement authorizing disclosure of that individual's record in the accompanying person's presence; and

(7) Any additional requirements that must be satisfied in order to provide information about or to grant access to the requested record or information.

(b) The following methods of access to records or information pertaining to an individual and contained in a system of records may be available to that individual depending on the circumstances of a particular request:

(1) A copy of the record may be enclosed with the initial response in accordance with paragraph (a) of this section;

(2) Inspection in person may be arranged during the regular business hours of the DOE in the office specifed by the Privacy Act Officer;

(3) Transfer of records to a Federal facility more convenient to the individual may be arranged, but only if the Privacy Act Officer determines that

a suitable facility is available, that the individual's access can be properly supervised at that facility, and that transmittal of the records or information to that facility will not unduly interfere with operations of the DOE or involve unreasonable costs, in terms of money or manpower; and

(4) The requested number of copies in addition to the initial copy may be mailed at the request of the individual, subject to payment of the fees prescribed in § 1008.13.

(c) If the Privacy Act Officer believes, based upon a recommendation of the System Manager, that disclosure of medical and/or psychological information directly to an individual could have an adverse effect upon that individual, the individual may be asked:

(1) To designate in writing a physician or mental health professional to whom he would like the records to be disclosed; or

(2) To submit a signed statement by his physician or a mental health professional indicating that, in his view, disclosure of the requested records or information directly to the individual will not have an adverse effect upon the individual.

(d) The Privacy Act Officer shall supply such other information and assistance at the time of an individual's review of his record as is necessary to make the record intelligible to the individual.

(e) The DOE reserves the right to limit access to original records by allowing access only to copies and abstracts of original records. This election would be appropriate, for example, when the record is in an automated data medium such as tape or disc, when the record contains information on or about individuals other than the individual to whom the record pertains, or when information is deleted under exemptions provided by the Privacy Act. In no event shall original records of the DOE be made available to the individual except under the immediate supervision of the Privacy Act Officer or his designee.

§ 1008.9 Action in response to a request for access: Initial denial of access.

(a) A request by an individual for information about or access to a record or information pertaining to that individual that is contained in a system of records may be denied only upon a determination by the appropriate System Manager, with the concurrence of the appropriate General Counsel, that:

(1) The record is subject to an exemption under § 1008.12 of this part or to an exemption claimed by another agency;

(2) The record is information compiled in reasonable anticipation of a civil action or proceeding; or

(3) The individual has unreasonably failed to comply with the procedural requirements of this part.

(b) The Privacy Act Officer shall give written notice of the denial of a request of information about or access to records or information pertaining to the individual and contained in a system of records. Such written notice shall be sent by certified or registered mail, return receipt requested and shall include the following information:

(1) The System Manager's name and title;

(2) The reasons for the denial, including citation to the appropriate sections of the Privacy Act and this part; and

(3) Notification of the individual's right to appeal the denial pursuant to § 1008.11 of this part and to administrative and judicial review under 5 U.S.C. 552a(g)(1)(B), as limited by 552a(g)(5).

(c) Where a record containing information about an individual also contains information not pertaining to him, the portion not pertaining to the individual shall not be disclosed, except to the extent that the information is available to any person under the Freedom of Information Act. If the record sought cannot be provided for review and copying in a meaningful form, the Privacy Act Officer may provide to the individual a report of the information pertaining to the individual that is contained in the record, which report shall be complete and accurate in all material aspects.

(d) Nothing in this section shall:

(1) Require the furnishing of information or records that are not retrieved by the name or by some other identifying number, symbol or identifying particular of the individual making the request;

(2) Prevent a System Manager from waiving any exemption authorizing the denial of records, in accordance with § 1008.12.

§ 1008.10 Action in response to a request for correction or amendment of records.

(a) The Privacy Act Officer must respond in writing to the requester for amendment of a record within 10 working days of receipt. This response shall inform the requester of the decision whenever possible.

(b) If the decision cannot be reached within 10 working days, the requester shall be informed of the reason for delay and the date (within 20 working days) it is expected that the decision will be made.

(c) The Privacy Act Officer, consistent with the recommendation of the System Manager or Managers, as concurred in by the appropriate General Counsel, if appropriate, shall do one of the following:

(1) Instruct the System Manager to make the requested correction or amendment; and advise the individual in writing of such action, providing either a copy of the corrected or amended record, or a statement as to the means whereby the correction or amendment was accomplished in cases where a copy cannot be provided (for example, erasure of information from a record maintained only in an electronic data bank); or

(2) Inform the individual in writing that his request is denied in whole or in part. Such denial shall be sent by certified or registered mail, return receipt requested, and shall provide the following information:

(i) The System Manager's name and title;

(ii) The reasons for the denial, including citation to the appropriate sections of the Act and this part; and

(iii) Notification of the individual's right to appeal the denial pursuant to § 1008.11 of this part and to administrative and judicial review under 5 U.S.C. 552a(g)(1)(B), as limited by 5 U.S.C. 552a(g)(5).

(iv) Notification of the right of the individual to submit a statement of disagreement consistent with § 1008.11(g).

(b) Whenever an individual's record is amended pursuant to a request by that individual, the Privacy Act Officer or the System Manager, as appropriate, shall notify all persons and agencies to which the amended portion of the record had been disclosed prior to its amendment, if an accounting of such disclosure was required by the Act. The notification shall request a recipient agency maintaining the record to acknowledge receipt of the notification, to correct or amend the record and to apprise an agency or person to which it had disclosed the record of the substance of the amendment.

(c) The following criteria will be taken into account by the DOE in reviewing a request for amendment:

(1) The sufficiency of the evidence submitted by the individual;

(2) The factual accuracy of the information;

(3) The relevance and necessity of the information in relation to the purpose for which it was collected;

(4) If such information is used in making any determination about the

individual, whether the information is as accurate, relevant, timely, and complete as is reasonably necessary to assure fairness to the individual in such determination;

(5) The degree of possibility that denial of the request could unfairly result in a determination adverse to the individual;

(6) The nature of the record sought to be corrected or amended; and

(7) The propriety and feasibility of complying with the specific means of amendment requested by the individual.

(d) The DOE will not undertake to gather evidence for the individual, but does reserve the right to verify the evidence that the individual submits.

(e) Amendment of a record requested by an individual may be denied upon a determination that:

(1) The individual has failed to establish, by a preponderance of the evidence, the propriety of the amendment in relation to the criteria stated in paragraph (c) of this section;

(2) The record sought to be amended was compiled in a terminated judicial, quasi-judicial or quasi-legislative proceeding to which the individual was a party or participant;

(3) The record sought to be amended is the subject of a pending judicial, quasi-judicial or quasi-legislative proceeding to which the individual is a party or participant;

(4) The amendment would violate a duly enacted statute or promulgated regulation;

(5) The individual has unreasonably failed to comply with the procedural requirements of this part; or

(6) The record has been properly exempted from the provisions of subsection (d) of the Privacy Act.

(f) Nothing in this section shall restrict the DOE from granting in part or denying in part a request for amendment of records.

§ 1008.11. Appeals of denials of requests pursuant to § 1008.6.

(a) Any individual may appeal the denial of a request made by him for information about or for access to or correction or amendment of records. An appeal shall be filed within 30 calendar days after receipt of the denial. When an appeal is filed by mail, the postmark is conclusive as to timeliness. The appeal shall be in writing. The words "PRIVACY ACT APPEAL" should appear in capital letters on the envelope and the letter. The appeal must be signed by the individual and shall be filed, as appropriate, with the Assistant Director for Agency Compliance and Evaluation, Office of Personnel Management (OPM), 1900 E Street, NW., Washington, DC 20415, or the Director, Office of Hearings and Appeals (OHA), Department of Energy, Headquarters, Washington, DC. For records maintained in government-wide systems of records reported by OPM, appeals shall be directed to the Assistant Director for Agency Compliance and Evaluation, OPM.

(b) An appeal not addressed and marked as specified in paragraph (a) of this section shall be forwarded immediately to the Assistant Director for Agency Compliance and Evaluation, OPM, or the Director, OHA. An appeal that is not properly addressed by an individual shall not be deemed to have been received for purposes of measuring the time periods in this section until actual receipt of the appeal by the Assistant Director, OPM, or the Director, OHA. In each instance when an appeal so forwarded is received, the individual filing the appeal shall be notified that the appeal was improperly addressed and the date when the appeal was received by the Assistant Director, OPM, or the Director, OHA.

(c) The appeal shall include the following:

(1) A copy of the original request for access of for amendment;

(2) A copy of the initial denial; and

(3) A statement of the reasons why the initial denial is believed to be in error.

(d) The records or record to which the individual was denied access, of which was requested to be corrected or amended, will be supplied to the appropriate appeal authority by the Privacy Act Officer who issued the initial denial. While such records normally will comprise the entire record on appeal, the appeal authority may seek such additional information as is necessary to assure that the final determination is fair and equitable.

(e) No personal appearance or hearing on appeal will be allowed.

(f) The appropriate appeal authority for DOE records shall act upon the appeal and issue a final determination in writing no later than 20 working days from the date on which the appeal is received. However, the appeal authority may extend the ten-day period upon a determination that a fair and equitable review cannot be made within that period. In such cases the individual shall be advised in writing of the reason for the extension and of the estimated date by which a final determination will be issued. The final determination shall be issued not later than the 30th working day after receipt of the appeal unless unusual circumstance, as defined in § 1008.7, are present, whereupon an additional 30 days may be extended.

(g) If an appeal of a denial of access is granted, a copy of the determination shall be transmitted promptly to the individual, the Privacy Act Officer and the appropriate System Manager. Upon receipt of the determination, the Privacy Act Officer promptly shall take action consistent with § 1008.8.

(h) If an appeal of a denial of correction or amendment is granted, the final determination shall identify the specific corrections or amendments to be made. A copy of the determination shall be transmitted promptly to the individual, the Privacy Act Officer and the appropriate System Manager. Upon receipt of the determination, the Privacy Act Officer promptly shall take steps to insure that the actions set forth in § 1008.10 (a) and (b) are taken.

(i) If the appeal of a denial of access is denied, the final determination shall state the reasons for the denial and shall be transmitted promptly to the individual, the Privacy Act Officer and the appropriate System Manager. The determination shall also include a statement identifying the right of the individual to administrative and judicial review pursuant to 5 U.S.C. 552a(g)(1)(B) as limited by 5 U.S.C. 552a(g)(5).

(j) If the appeal of a denial of correction or amendment is denied, the final determination shall state the reasons for the denial and shall be transmitted promptly to the individual, the Privacy Act Officer and the appropriate System Manager.

(1) The determination also shall include the following:

(i) Notice of the right of the individual to file with the Privacy Act Officer a concise signed statement of reasons for disagreeing with the final determination, receipt of which statement will be acknowledged by the Privacy Act Officer.

(ii) An indication that any disagreement statement filed by the individual will be noted and appended to the disputed record and that a copy of the statement will be provided by the Privacy Act Officer or the System Manager, as appropriate, to persons and agencies to which the record is disclosed subsequent to the date of receipt of such statement;

(iii) An indication that the DOE shall append to any disagreement statement filed by the individual a copy of the final determination or a summary thereof, which determination or summary also will be provided to persons and agencies to which the disagreement statement is disclosed; and,

(iv) A statement of the right of the individual to administrative and judicial review under 5 U.S.C 552a(g)(1)(B), as limited by 5 U.S.C. 552a(g)(5).

(2) Although a copy of the final determination or a summary thereof will be treated as part of the individual's record for purposes of disclosure in instances where the individual has filed a disagreement statement, it will not be subject to correction or amendment by the individual.

(3) Where an individual files a statement of disagreement consistent with subparagraph (1) of this paragraph, the Privacy Act Officer shall take steps to insure that the actions provided in subparagraphs (1) (i), (ii) and (iii) are taken.

§ 1008.12 Exemptions.

(a) *General exemptions*—(1) *Generally.* 5 U.S.C. 552a(j)(2) allows the exemption of any system of records within the DOE from any part of section 552a except subsections (b), (c) (1) and (2), (e)(4) (A) through (F) (e)(6), (7), (9), (10), and (11), and (i) if the system of records is maintained by a DOE component which performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and which consists of (A) information compiled for the purpose of identifying individual criminal offenders and alleged offenders; (B) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (C) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

(2) *Applicability of general exemptions to DOE systems of records*—(i) *Investigative Files of the Inspector General (DOE–54).* This system of records is being exempted pursuant to subsection (j)(2) of section 552a in order to aid the Office of the Inspector General in the performance of its law enforcement function. The system is exempted from subsections (c) (3) and (4); (d)(1)–(4); (e)(1)–(3); (4)(G), (H), and (I); (5) and (8); and (g). The system is exempt from these provisions for the following reasons: Notifying an individual at the individual's request of the existence of records in an investigative file pertaining to such individual, or granting access to an investigative file could (A) interfere with investigative and enforcement proceedings and with co-defendants' right to a fair trial; (B) disclose the identity of confidential sources and reveal confidential information supplied by these sources; and (C) disclose investigative techniques and procedures.

(b) *Specific exemptions* (1) *Generally.* 5 U.S.C. 552a(k) allows the exemption of any system of records within the DOE from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) of section 3 of the Privacy Act, if the system of records consists of:

(i) Records that are specifically authorized under criteria established under statute or an Executive Order to be kept secret in the interest of national defense or foreign policy, and are in fact properly classified pursuant to such statute or Executive Order. Restricted Data and Formerly Restricted Data under the Atomic Energy Act of 1954, as amended, are included in this exemption.

(ii) Investigatory material compiled for law enforcement purposes: *Provided, however,* That if any individual is denied any right, privilege, or benefit to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence.

(iii) Records by statute to be maintained and used solely as statistical records.

(iv) Investigatory material compiled solely for the purposes of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence.

(v) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service, the disclosure of which would compromise the objectivity or fairness of the testing or examination process.

(2) *Applicability of specific exemptions to DOE systems of records.*—(i) *Exempt under 5 U.S.C. 552a(k)(2) (see subparagraph (1)(ii) of this paragraph) and (k)(5) (see subparagraph (1)(iv) of this paragraph).* The following systems of records are exempted from 5 U.S.C. 552a(c)(3) (accounting of disclosures), (d) (access to records), and (e)(1) (types of information maintained). The reasons for asserting exemption (k)(2) are: To prevent subjects of investigation from frustrating the investigatory process; to insure the proper functioning and integrity of law enforcement activities, to prevent disclosure of investigative techniques; and to maintain the ability to obtain necessary information. The reasons for asserting the (k)(5) exemption are: To maintain the ability to obtain candid and necessary information; to fulfill commitments made to sources to protect the confidentiality of information; to avoid endangering these sources; and, to facilitate proper selection or continuance of the best applicants or persons for a given position or contract:

(A) DOE-1, DOE Personnel and General Employment Records (only personnel investigative records concerning current and former DOE employees and applicants for employment by DOE);

(B) DOE-43, Personnel Security Clearance Files;

(C) DOE-54, Investigative Files of the Inspector General (only investigative records concerning DOE employees, past and present).

(ii) *Exempt under 5 U.S.C. 552a(k)(1) subparagraph (1)(i) of this paragraph), (k)(2) (see subparagraph (1)(ii) of this paragraph) and (k)(5) (see subparagraph (1)(iv) of this paragraph).* The following systems of records are exempted from 5 U.S.C. 552a(c)(3) (accounting of disclosures), (d) (access to records), (e)(1) (type of information maintained):

(A) Alien Visits and Participation (DOE–52).

(B) Clearance Board Cases (DOE–46).

(C) Security Correspondence (DOE–49).

(D) Foreign Travel Records (DOE–27).

(E) Legal Office Claims, Litigations, Criminal Violation, Patents, and other Legal Files (DOE–41).

(F) Personnel Security Clearance Files (DOE–43).

(H) Personnel Security Clearance Index (Automated) (DOE–42).

(I) Special Access Authorization for Categories of Classified Information (DOE–44).

The reasons for asserting the (k)(1) exemption are to prevent serious damage to the national defense or foreign policy that could arise from providing individuals access to classified information. The reasons for asserting exemptions (k)(2) and (k)(5) for these systems are the same as those set

forth in subparagraph (2)(v) of this paragraph

(iii) *Exempt under 5 U.S.C. a(k)(5) (see subparagraph (1)(iv) of this paragraph and (k)(6) (see subparagraph (1)(v) of this paragraph).* The following systems of records are exempt from 5 U.S.C. 552a(c)(3) (accounting of disclosures), (d) (access to records), and (e)(1) (type of information maintained:

(A) DOE Personnel: Supervisor-Maintained Personnel Records (DOE–2).

(B) Applications for DOE Employment (DOE–4).

(C) DOE Personnel and General Employment Records (DOE–1).

The reason for asserting the (k)(5) exemption is the same as that set forth in subparagraph (2)(i) of this paragraph. The reasons for asserting the (k)(6) exemption are to protect the integtity of the personnel testing and evaluation process and to avoid providing individuals with unfair advantage, by premature or unfair disclosure of testing or rating information.

(c) *Application of exemptions to particular requests.* (1) The Privacy Act Officer, consistent with the recommendation of the System Manager and with concurrence of the appropriate General Counsel, may make available records which the DOE is authorized to withhold under this section.

(2) With respect to records containing material or information that would reveal the identity of a source who was given an assurance of confidentiality, a determination to make records available pursuant to subparagraph (1) of this paragraph shall be made only if the source consents to the release of such information to the individual, or if it is determined that the material or information is not adverse or detrimental to the individual, or for good cause shown. The exercise of discretion with respect to waiver of the exemption shall be final.

(3) Prior to making a determination to deny access to a record in a system of records covered by exemption (k)(1) for classified material (see paragraph (b)(1)(i) and (b)(2)(iii) of this section), the System Manager shall consult with the Director, Division of Classification, to verify the current classification status of the information in the requested record.

§ 1008.13 Fees.

(a) The only fees to be charged to or collected from an individual under the provisions of this part are for copying records at the request of the individual. The fee charged shall be consistent with the fee schedule set forth in paragraph (b) of this section.

(1) No fees shall be charged or collected for the following: Search for and retrieval of records; review of records; copying by the DOE incident to granting access; copying at the initiative of the DOE without a request from the individual; copying when the aggregate of fees for copying is $25 or less; time spent providing copies; transportation of records and personnel; and first class postage.

(2) It is the policy of the DOE to provide an individual with one copy of each record corrected or amended pursuant to request without charge.

(3) As required by the Office of Personnel Management in its published regulations implementing the Act, the DOE will charge no fee for a single copy of a personnel record covered by that Commission's Government-wide published notice of systems of records.

(b) The schedule of fees is as follows:

(1) $.10 per copy of each page.

(2) For other forms of copying and other forms of materials (e.g., cassettes, computer materials), the direct cost of the materials, personnel, and equipment shall be charged, but only with prior specific approval of the person making the request, when such charges would be in excess of $25.

(c) The Privacy Act Officer may, upon application by an individual, furnish any records without charge or at a reduced rate, if he determines that such waiver or reduction of fees is in the public interest.

(d) Payment shall be made by check or money order payable to the United States Department of Energy.

(e) Advance payment of all or part of the fees may be required at the discretion of the Privacy Act Officer. Unless the individual requesting the copies specifically states that he is willing to pay whatever fees are assessed for meeting the request or, alternatively, specifies an amount in excess of $25 that he is willing to pay and which in fact covers the anticipated fees for meeting the request, a request that is expected to involve assessed fees in excess of $25 shall not be deemed to have been received, for purposes of the time periods specified in §§ 1008.7 and 1008.10 until the individual making the request is notified of the anticipated, cost, agrees to bear it, and makes any advance deposit required. Such notification shall be made by the Privacy Act Officer as promptly as possible after receipt of the request.

§ 1008.14 Requests under false pretenses.

Title 5 U.S.C. 552a(i)(3) provides that any person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdeameanor and fined not more than $5,000.

Subpart C—Disclosure to Third Parties

§ 1008.15 Prohibition against disclosure.

Except as provided in § 1008.16, the DOE shall not disclose any record which is contained in a system of records, by any means of communication, to any agency or to any person other than the individual who is the subject of the record.

§ 1008.16 Conditions of disclosure.

(a) Notwithstanding the prohibition contained in § 1008.15, the DOE may disclose records covered by this part to the individual to whom the record pertains or to an agency or to a person other than the individual where he has given his prior written consent to the disclosure or has made a written request for such disclosure.

(b) Notwithstanding the prohibition contained in § 1008.15 the DOE may also disclose records covered by this part whenever the disclosure is:

(1) To officers and employees of the DOE who have a need for the record in the performance of their duties;

(2) Required under the Freedom of Information Act (5 U.S.C. 552);

(3) For a routine use as defined in § 1008.2 and described in the Federal Register notice for that system of records;

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13 of the United States Code;

(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value;

(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States or a civil or criminal law enforcement activity if the activity is authorized by law and if the head of the agency or instrumentality has made a written request to the DOE specifying the particular portion desired and the

law enforcement activity for which the record is sought;

(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of such individual;

(9) To either House of Congress, or to any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee, to the extent of matter within its jurisdiction;

(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office;

(11) Pursuant to the order of a court of competent jurisdiction.

(c) Notwithstanding the prohibition contained in section § 1008.15, the DOE may also disclose records covered by this part in the following additional circumstances:

(1) 5 U.S.C. 552a(c)(4) requires dissemination of a corrected or amended record or notation of a disagreement statement by the DOE in certain circumstances;

(2) To the Office of Management and Budget in the performance of its duties under section 6 of the Privacy Act, which authorizes continuing oversight and assistance in implementation of the Act, which may necessitate the release of records or information to that Office.

§ 1008.17 Accounting for disclosures.

(a) For each disclosure of information contained in a system of records under his control, except disclosures to authorized officers and employees of DOE and disclosures required by the Freedom of Information Act, the appropriate System Manager shall keep an accurate accounting of:

(1) The date, nature, and purposes of each disclosure of a record made to any person or to another agency; and

(2) The name and address of the person or agency to which the disclosure was made.

(b) The accounting shall be retained for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made.

(c) The accounting described in paragraph (a) of this section shall be made available to the individual named in the record upon written request to the Privacy Act Officer at the appropriate DOE location listed at § 1008.2(e). However, the accounting shall not be revealed with respect to disclosures made under § 1008.16(b)(7) of this part, pertaining to law enforcement activity; or with respect to disclosures involving system of records for which DOE had claimed an exemption from certain requirements of the Act, as provided in § 1008.12; or with respect to which another agency has claimed an exemption.

(d) Whenever an amendment or correction of a record or a notation of dispute concerning the accuracy of records is made by the DOE in accordance with § 1008.10(a)(2)(iv) and § 1008.11(g), DOE shall inform any person or other agency to whom the record was previously disclosed if an accounting of the disclosure was made pursuant to the requirements of paragraph (a) of this section, unless the disclosure was made pursuant to section § 1008.16(b)(7); or the disclosure involved a system or records of which DOE has claimed an exemption from certain requirements of the Act, as provided in § 1008.12; or with respect to which another agency has claimed an exemption.

(e) The System Manager shall make reasonable efforts to serve notice on an individual when any record containing information about such individual in a DOE system of records is disclosed to any person under compulsory legal process when such process becomes a matter of public record.

(f) Prior to disclosing any record about an individual to any person other than an agency, unless the disclosure is pursuant to the Freedom of Information Act, the System Manager shall make reasonable efforts to assure that each record is accurate, complete, timely, and relevant for DOE's purposes.

Subpart D—Maintenance and Establishment of systems of Records

§ 1008.18 Content of systems of records.

(a) The DOE shall maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose DOE is required to accomplish by statute or by Executive Order of the President, unless an exemption to this requirement has been claimed by DOE, as provided in § 1008.12, or by another agency.

(b) The DOE shall maintain no record describing how any individual exercises rights guaranteed by the First Amendment unless expressly authorized by statute or by the individual about whom the record is maintained or unless it is pertinent to and within the scope of an authorized law enforcement activity.

(c) The DOE shall maintain all records that are used by it to make any determination about any individual with such accuracy, relevance, timeliness and completeness as is reasonably necessary to assure fairness to the individual in such determination.

§ 1008.19 Collection of information by DOE about an individual for a system of records.

(a) The DOE shall collect information, to the greatest extent practicable, directly from the subject individual when the use of the information may result in adverse determinations about an individual's rights, benefits and privileges under Federal programs, unless an exemption from the Act to this requirement has been claimed by DOE as provided in § 1008.12, or by another agency.

(b) Unless an exemption from the Act has been claimed by DOE, as provided in § 1008.12, or by another agency, DOE shall inform each individual whom it asks to supply information, on the form or other means by which it uses to collect the information, or on a separate form that can be retained by the individual, of the following:

(1) The authority (whether granted by statute or by Executive order of the President) that authorizes the solicitation of the information and whether the provision of such information is mandatory or voluntary;

(2) The principal purpose or purposes for which the information is intended to be used;

(3) The routine uses that may be made of the information, as published in the Federal Register pursuant to the requirements of the Act; and

(4) The effect on the individual, if any, of not providing all or any part of the requested information.

§ 1008.20 Use and collection of social security numbers.

(a) The System Manager of each system of records which utilizes social security numbers as a method of identification without statutory authorization or authorization by regulation adopted prior to January 1, 1975, shall revise the system to avoid future collection and use of the social security numbers.

(b) Heads of Headquarters Divisions and Offices and heads of the other DOE locations shall insure that employees authorized to collect information from individuals are advised that individuals may not be required to furnish social security numbers without statutory or regulatory authorization, and that individuals who are requested to provide social security numbers voluntarily must be advised that furnishing the number is not required and that no penalty or denial of benefits will flow from the refusal to provide it.

§ 1008.21 Public notice of systems of records.

(a) The DOE shall publish in the Federal Register at least annually a notice of the existence and character of each of its systems of records, which notice shall include:

(1) The name and location of the system;

(2) The categories of individuals on whom records are maintained in the system;

(3) The categories of records maintained in the system;

(4) Each routine use of the records contained in the system, including the categories of user and the purpose of such use, subject to paragraph (d) of this section;

(5) The policies and practices of the DOE regarding storage, retrievability, access controls, retention, and disposal of the records;

(6) The title and business address of the DOE official who is responsible for the system of records;

(7) The DOE procedures whereby an individual can be notified at his request if the system of records contains a record pertaining to him;

(8) The DOE procedures whereby an individual can be notified at his request about how he can gain access to any record pertaining to him contained in the system or records, and how he can contest its content; and

(9) The categories of source of records in the systems.

(b) Notwithstanding the requirements of paragraph (a) of this section, the notice of systems of records shall not necessarily include the information in paragraphs (a)(7)–(9) of this section if DOE has claimed a general or specific exemption from the requirements of the Act, as provided in § 1008.12, or if such exemptions have been claimed by another agency.

(c) Copies of the notices as printed in the Federal Register shall be available at the DOE locations listed at § 1008.2(c). Requests by mail for copies of such notices should be sent to Privacy Act Officer, Headquarters, U.S. Department of Energy, Washington, D.C. 20585. The first copy will be furnished free of charge. For each additional copy, the costs of printing and handling may be charged.

(d) DOE shall publish in the Federal Register notice of any new routine use or intended routine use of a record in the system of records, at least 30 calendar days prior to the implementation of any new routine use of a record in a system of records, or at least 30 calendar days prior to publication of the annual notice of such routine uses, as provided in paragraph (a) of this section, an opportunity for interested persons to submit written comments consisting of data, views, or arguments regarding such use to DOE, shall be provided.

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Federal Register

Tuesday
May 27, 1980

Part V

Department of Housing and Urban Development

Office of Assistant Secretary for Housing—Federal Housing Commissioner

Annual Contributions for Operating Subsidy; Performance Funding System; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 890

[Docket No. R-80-814]

Annual Contributions for Operating Subsidy; Performance Funding System

AGENCY: Department of Housing and Urban Development (HUD).

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend 24 CFR Part 890 to establish a new procedure for the calculation of the allowable utilities consumption level used in the Performance Funding System (PFS). The new procedure will provide a method of adjusting the PHA's level of utilities consumption based upon a comparison of heating degree days of a Fixed Base Period.

DATE: COMMENTS DUE: July 28, 1980.

ADDRESS: Written comments and suggestions should be filed with the Rules Docket Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Milton Slifkin, Financial Management Procedures Branch, Office of Public Housing, HUD, Washington, D.C. 20410, (202) 426-0744 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The Department published on September 6, 1977 (42 FR 44550) an Interim Rule dealing with the Utilities Base Consumption Period (Base Period) used to calculate the Utilities Expense Level (UEL) for Public Housing Agency (PHA) fiscal years beginning on or after July 1, 1977. The Interim Rule amended HUD policy which provided that the UEL would be calculated by using the average consumption over a rolling 36-month period ending six months prior to the PHA's requested Budget Year. However, due to the severely cold winter of 1976-1977, HUD determined that it would be improper to include the impact of that winter in the utilities Base Period because of its disproportionate effect on the UEL. Therefore, the Interim Rule, published September 6, 1977, stated that the Base Period for PHA fiscal years beginning July 1, 1977, and thereafter would exclude that winter.

Since publication of the Interim Rule, the Department has determined that a new approach, the 30-Year Heating Degree Day System (30-HDDS), would be more equitable than the Fixed Base System because it (1) produces more reasonable projections because of the greater number of years involved than in the base period used in the Fixed Base System, and (2) recognizes that the base period used in the Fixed Base System was limited to the consumption in winters that on the average were warmer than normal.

HUD stated in the preamble to the Interim Rule that it anticipated the introduction of an additional adjustment, dependent upon fund availability, which would be applied to the Fixed Base Period as defined in the Interim Rule. The additional adjustment factor was to assure that PHAs would be funded at a normal level of utilities consumption.

HUD received five communications in response to the Interim Rule. Each communciation contained numerous comments and recommendations. A discussion of those comments and of the changes in the rule follows.

The principal comments suggested that the Interim Rule which established the Fixed Base Period be rescinded for the following reasons:

1. The Fixed Base Period as currently structured does not include the winter of 1976-1977 or subsequent winters, and therefore defeats the purpose of producing a projection of allowable utility comsumption which is most reflective of PHA consumption experience.

2. To be more equitable, the base period should be extended over a longer period of time.

After lengthy discussion, both within and outside the Department, it has been determined that the adjustment mentioned in the Interim Rule should consider the following:

1. Local conditions.

. The allowable utility level should be based on a longer period of time than the 36 months Fixed Base Period so as to negate unusual effects of any abnormally cold or warm seasonal changes.

3. The period should, to the extent possible, be representative of an average winter.

4. The revised system should not be complex nor administratively difficult to administer.

5. The revised system should alter the current utilities system as little as possible.

In evaluating the above concerns relating to the Interim Rule, it has been determined that the most expeditious way of addressing the concerns expressed in the comments, and of meeting the Department's objectives of devising an allowable utilities consumption system that is both equitable and workable is to revise the Interim Rule and establish a 30-Year Heating Degree Day System (30-HDDS) based upon a comparison of heating degree days over a period of 30 years (1941 through 1970) with heating degree days utilized in the Fixed Base Period. Section 890.107 accordingly would be revised to provide an adjustment to the consumption experienced during the Base Periods prescribed by § 890.107(c)(1) or (2). The purpose of this adjustment is to establish an allowable utilities consumption level based upon a long-term period which reflects more closely a normal level of consumption, and to provide PHAs with a stable projection of utility consumption. This adjustment (Change Factor) is the ratio of the average annual heating degree days (HDD) for the 30-year period from 1941 through 1970 to the HDD of the PHA's Fixed Base Period (30-year average HDD÷Fixed Base Period average HDD). The 30-year period is considered to be sufficiently long so as to level out any abnormalities that may have ocurred in a particular year(s).

The key elements of the 30-HDDS are as follows:

a. Since the adjustment (Change Factor) is solely to reflect the relationship of the heating degree days for the two periods (Fixed Base Period vs. 30-year period), only those utilities used for heat shall be adjusted by the Change Factor. Therefore, a PHA will adjust the total average consumption experienced during the Fixed Base Period of any utility used for heating by the Change Factor provided by HUD. No Change Factor less than 1.00 would be used by a PHA.

b. The consumption level for any utility not used for heating would be maintained at the average level which occurred during the prescribed Fixed Base Period, since increases in consumption of these utilities are, in general, extremely minimal (1% or less per year).

c. The consumption levels for heating and non-heating utilities would become the permanent allowable Utilities Consumption Level.

d. The average consumption of all heating and non-heating utilities (adjusted by the Change Factor as appropriate for heating utilities) would then be multiplied by the cost rate of the utilities.

e. There would be adjustments to each of the consumption components at the end of the PHA's fiscal year based upon actual consumption; e.g., projected consumption—1,000 gallons of oil; actual

consumption 1,100 gallons. The PHA would receive 50 percent of cost attributable to excess consumption of 100 gallons. If the PHA consumed 900 gallons, HUD would retain 50 percent of the savings accrued due to reduced consumption, and the PHA would retain 50 percent. The same 50/50 adjustment would apply to utilities which are not used for heat; e.g., water, sewer, and in some cases, electricity. Under the current Regulation, the PHA can retain only 25 percent of the savings. Sections 890.110(c)(3) and (4) will be revised to reflect this change in percentages.

f. There would continue to be a 100 percent adjustment for an increase or decrease in utility rates.

g. Where consumption records are not available, the actual utilities expenses incurred during the PHA fiscal years which ended December 31, 1975, March 31, 1976, June 30, 1976 or September 30, 1976, would be used with no further adjustment. In these cases, the PHA would be allowed to reconstruct consumption data based on the experience of comparable PHAs.

h. The 30-HDDS will be first applicable to PHA fiscal years beginning January 1, 1980, and thereafter. The 50/50 adjustment is first applicable to utility adjustments submitted for PHA fiscal years ending December 31, 1980, March 31, 1981, June 30, 1981 and September 30, 1981, and thereafter.

i. Heating Degree Days are the annual arithmetic sum of the positive differences (those under 65 degrees) of the average of the lowest and highest daily outside temperatures in degree Fahrenheit, subtracted from 65 Degrees Fahrenheit. For example: The Heating Degrees Days for one day would be as follows:

	Degrees
Highest temperature reading	50
Lowest temperature reading	30
Subtotal	80
65 deg. Fahrenheit base	65
Average temperature of the day (50+30÷2)	40
Heating degree days for the one day (65—40)	25

j. A listing of the Change Factors for a representative sample of PHAs is listed below. If a PHA's Change Factor is not listed and the PHA is desirous of knowing its Change Factor, the information may be obtained by calling Milton Slifkin (202) 426-0744. (This is not a toll-free number).

Public housing agency	Change factor
Birmingham, AL	1.043
Fort Payne, AL	1.052
Mobile, AL	1.195
Montgomery, AL	1.037
Russellville, AL	1.056
Tuscaloosa, AL	1.009
Papago, AZ	1.000
Little Rock, AR	1.071
Colexico, CA	1.000
Fresno, CA	1.000
Los Angeles, CA	1.000
Oakland, CA	1.000
Oxnard, CA	1.000
San Francisco, CA	1.000
Yolo County, CA	1.000
Denver, CO	1.000
Trinidad, CO	1.000
Hartford, CT	1.023
Middletown, CT	1.044
New Haven, CT	1.041
Willimantic, CT	1.033
Wilmington, DE	1.083
Washington, DC	1.064
Dade County, FL	1.274
Fort Myers, FL	1.230
Lakeland, FL	1.196
Levy, FL	1.154
Tampa, FL	1.196
Athens, GA	1.032
Atlanta, GA	1.032
Douglas, GA	1.145
Gainsville, GA	1.041
Lyons, GA	1.222
McDonough, GA	1.113
Quitman, GA	1.118
Rome, GA	1.068
Savannah, GA	1.222
Hawaii, HI	1.000
Champaign County, IL	1.026
Chicago, IL	1.026
E. St. Louis, IL	1.028
Effingham County, IL	1.048
Franklin County, IL	1.055
Joliet, IL	1.035
Madison, IL	1.027
Manon County, IL	1.042
Peoria, IL	1.044
Saline, IL	1.055
Williamson County, IL	1.032
Winnebago, IL	1.004
Covington, KY	1.057
Louisville, KY	1.095
Middlesborough, KY	1.032
Somerset, KY	1.037
New Iberia, LA	1.195
New Orleans, LA	1.139
Baltimore, MD	1.070
Cumberland, MD	1.046
Boston, MA	1.018
Lowell, MA	1.014
New Bedford, MA	1.021
Worcester, MA	1.000
Big Rapids, MI	1.001
Detroit, MI	1.036
Inkster, MI	1.028
Ypsilanti, MI	1.036
Hibbing, MN	1.000
Minneapolis, MN	1.007
St. Paul, MN	1.018
Hattiesburg, MS	1.090
Columbia, MO	1.045
Kansas City, MO	1.034
St. Louis, MO	1.045
Omaha, NE	1.032
Las Vegas, NV	1.000
Dover, NH	1.020
Manchester, NH	1.109
Camden, NJ	1.076
Irvington, NJ	1.032
Jersey City, NJ	1.032
Newark, NJ	1.032
Passaic, NJ	1.036
Paterson, NJ	1.032
Perth Amboy, NJ	1.073
Trenton, NJ	1.076
Albany, NY	1.025
Binghampton, NY	1.020
Buffalo, NY	1.018
Hempstead, NY	1.074
Kingston, NY	1.015
New York, NY	1.074
Rochester, NY	1.008
Troy, NY	1.022
Burlington, NC	1.042
Greensboro, NC	1.042
Kinston, NC	1.167
Lumberton, NC	1.132
New Bern, NC	1.167
Winston Salem, NC	1.042
Turtle Mountain, ND	1.002
Akron, OH	1.041
Cincinnati, OH	1.020
Columbus, OH	1.051
Dayton, OH	1.020
Lorain, OH	1.026
Youngstown, OH	1.045
Creek Nation, OK	1.078
Tulsa, OK	1.000
Douglas County, OR	1.000
Chester, PA	1.052
Easton, PA	1.009
Fayette County, PA	1.024
Harrisburg, PA	1.024
Lackawanna, PA	1.034
Mercer County, PA	1.027
Mifflin County, PA	1.024
Montour County, PA	1.027
Philadelphia, PA	1.060
Pittsburgh, PA	1.023
Washington, PA	1.022
Pawtucket, RI	1.046
Charleston, SC	1.178
Clinton, TN	1.030
Franklin, TN	1.047
Jackson, TN	1.039
LaFollette, TN	1.032
Maryville, TN	1.034
Memphis, TN	1.019
Nashville, TN	1.046
Belton, TX	1.083
Corsicana, TX	1.083
Dallas, TX	1.094
Fort Worth, TX	1.094
Gonzales, TX	1.132
Harlingen, TX	1.083
Houston, TX	1.118
Laredo, TX	1.154
McAllen, TX	1.000
San Antonio, TX	1.132
Temple, TX	1.083
Waxahachie, TX	1.023
Wichita Falls, TX	1.070
Newport News, VA	1.084
Norfolk, VA	1.084
Richmond, VA	1.099
Roanoke, VA	1.046
Bremerton, WA	1.009
King County, WA	1.000
Tacoma, WA	1.000
Yakima Nation, WA	1.008
Milwaukee, WI	1.023

3. The adoption of the 30-HDDS has necessitated a rewriting and/or a reorganization of § 890.107.

A finding of inapplicability respecting the National Environmental Policy Act of 1969 has been made in accordance with HUD procedures. A copy of this finding of inapplicability is available for public inspection during business hours in the Office of the Rules Docket Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 7th Street SW., Washington, D.C. 20410.

This rule is not listed in the Department's semiannual agenda of signficant rules, published pursuant to Executive Order 12044.

In consideration of the foregoing, the Department, therefore, proposes to amend 24 CFR Part 890 as follows:

§ 890.1021 [Amended]

1. Section 890.102 is amended to add the following definitions:

* * * * *

(t) *Fixed Base Period.* The period of time, prescribed in § 890.107(c)(1), used to determine the Utilities Consumption Level used to compute the allowable Utilities Expense Level.

(u) *Change Factor.* The ratio of the average annual heating degree days (HDD) for the 30-year period from 1941 through 1970 to the average annual HDD of the PHA's Fixed Base Period. (30 year average HDD ÷ Fixed Base Period average HDD).

* * * * *

2. Section 890.107 is revised to read as follows:

§ 890.107 Computations of utilities expense level.

(a) *General.* In recognition of the rapid rises which occur in utilities cost and the wide diversity among PHAs as types of utilities services used, and the methods of payment, and the fact that utilities rates charged by suppliers are beyond the control of the PHA, the PFS treats utilities expenses separately. Utilities expenses are excluded from the PHA's Allowable Expense Level. The PFS computes the amount of operating subsidy based upon a calculated utilities expense of each PHA. The PHA's Utilities Expense Level for the Requested Budget Year shall be computed by multiplying the average Utilities Consumption Level per unit per month for each utility, determined as provided in paragraphs (c) and (d) of this section, by the projected utility rate determined as provided in paragraph (b) of this section.

(b) *Utilities rates.* The current applicable rates in effect at the time Operating Budget is submitted to HUD will be used as the utilities rates for the Requested Budget Year, except that, when the appropriate utility commission has, prior to the date of submission of the Operating Budget to HUD, approved and published rate increased to be applicable during the Requested Budget Year, the future approved rates may be used as the utilities rates for the entire Requested Budget Year.

(c) *Computatiuon of Utilities Consumption Level.* The Utilities Consumption Level used to compute the Utilities Expense Level of a PHA for the Requested Budget Year will be determined based upon the availability of consumption data. For projects where consumption data is available for the entire FIxed Base Period, the computation will be in accordance with paragraph (c)(1) of this section. For projects (other than New Projects) where the computation data is not available for the entire Fixed Base Period, the consumption will be in accordance with paragraph (c)(2) of this section. For New Projects the computation will be in accordance with paragraph (c)(3) of this section. The Utiltities Consumption Level for all of a PHA's projects is the sum of the amounts determined under paragraph (c)(1), (2) and (3) of this section.

(1) Fixed Base Period System. For projects with consumption data for the entire Fixed Base Period the Utilities Consumption Level is the average amount consumed per unit per month during the Fixed Base Period, adjusted in accordance with paragraph (d) of this section. This adjusted amount shall be the Utilities Consumption Level for all PHA fiscal years beginning January 1, 1980, and for all future fiscal years thereafter, until superseded by HUD. For PHA fiscal years beginning July 1, 1977, and thereafter, such Fixed Base Period shall be the respective 36-month periods given below:

PHA fiscal years		Fixed-base period	
Beginning	Ending	Begins	Ends
7/1	6/30	1/1/73	12/31/75
10/1	9/30	4/1/73	3/31/76
1/1	12/31	7/1/73	6/30/76
4/1	3/31	10/1/73	9/30/76

(2) Alternative methods where data is not available for the entire Fixed Base Period.

(i) If the PHA has not maintained or cannot recapture consumption data regarding a particular utility or utilities from its records for the Fixed Base Period mentioned in paragraph (c)(1) of this section, it shall submit consumption data for the last 24 months of its Fixed Base Period to the HUD Field Office for approval. If this is not possible, it shall submit consumption data for the last 12 months of its Fixed Base Period. The PHA also shall submit a written explanation of the reasons data for the Fixed Base Period are unavailable.

(ii) If a PHA has not maintained or cannot recapture consumption data for the specified Fixed Base Period of 36, 24, or 12 months, comparable consumption for the greatest of either 36, 24, or 12 months, as available, shall be used for the utility or utilities for which the data is lacking. The comparable consumption shall be estimated based upon the consumption experienced during the allowable Fixed Base Period of comparable project(s) with comparable utility delivery systems and occupancy.

(iii) If a PHA does not obtain the consumption data for the Fixed Base Period, either for its own project(s) or by using comparable consumption data, the actual PUM utility expenses stated in paragraph (e) of this section shall be used and no Change Factor shall be applied.

(3) Computation of Utilities Consumption Levels for New Projects.

(i) A New Project for the purpose of establishing the Fixed Base Period and the allowable Utilities Expense Level is defined as either: (A) A project which had not been in operation during the entire Fixed Base Period, or a project which enters management after the Fixed Base Period and prior to the end of the Requested Budget Year; or (B) a project which during or after the Fixed Base Period, has experienced conversion from one energy source to another; interruptible service; deprogrammed units; a switch from tenant-supplied to PHA-supplied utilities; or a switch from PHA-supplied to tenant-supplied utilities.

(ii) The actual consumption of New Projects shall be constructed so as not to distort the Fixed Base Period in accordance with a method prescribed by HUD.

(d) *Adjustment to utilities used for heating.* For projects with consumption data for the entire Fixed Base Period, and for New Projects, consumption of utilities used for heating shall be adjusted by a Change Factor as follows:

(1) *Adjustment of the Fixed Base Period data.*—(i) *Use of Change Factors.* A Change Factor has been developed which indicates the relationship of the average annual heating degree days for the 30-year period from 1941 through 1970 to the average annual heating degree days for the PHA Fixed Base Period. This Change Factor is to be used to establish an allowable Utilities Consumption Level based upon a long-term period which reflects closely a representative winter's consumption. The 30-year period is considered to be sufficiently long so as to level out any abnormalities that may have occurred in a particular year(s). The Change Factors have been developed by the National Climatic Center of the Department of Commerce for each established standard weather division of the country, by PHA fiscal year. Change Factors will be supplied by HUD to the PHAs. The larger the Change Factor, the greater the difference between the heating degree days of the Fixed Base Period and the 30-year period. When the Change Factor is greater than 1.00, the average annual heating degree days of the 30-year period are greater than the average annual heating degree days of the Fixed Base Period which means that on the average the weather experienced during the 30-year period was colder than that experienced during the Fixed Base Period. An example of the effect of

the Change Factor on the Fixed Base Period consumption is:

Assume:	
30-year period average annual heating degree days	4,000
Fixed base period average annual heating degree days	3,800
Fixed base period average annual consumption for heating purposes	[1]1,000
Results:	
Change factor is (4,000÷3,800)	1.05
Adjusted fixed base period average annual consumption for heating purposes (1,000×1.05)	[1]1,050

[1]Gallons.

(ii) *PHA fiscal years affected.* The Change Factor shall be used to compute the allowable Utilities Consumption Level submitted with the Operating Budgets for PHA Fiscal Years beginning January 1, 1980, April 1, 1980, July 1, 1980, and October 1, 1980, and thereafter.

(iii) *Application of Change Factor to consumption of the Fixed Base Period.* The Change Factor is to be applied only to the consumption readings of meters of utilities, or gallons of oil, or tons of coal used for the purpose of generating heat for dwelling units and other PHA associated buildings. The Change Factor shall not be applied to the consumption readings of meters of utilities not used for the purpose of generating heat; e.g., water and sewer or electricity used solely for non-heating purposes. The Change Factor shall be applied to the total consumption reading of meters of utilities, or gallons of oil, or tons of coal used for heating even though the same meter or same energy source is used for other purposes; e.g., heating and cooking gas usage metered on the same meter or oil used for space heating and also heating of water. Such consumption for each 12 month period of the Fixed Base Period shall be adjusted by the Change Factor. The adjusted consumption for each year shall be totalled. These totals then will be averaged. The consumption readings of meters of utilities not used for heating (not adjusted by the Change Factor) shall be included in the total consumption.

Example Showing Application of Change Factor

	Base year		
	1st year	2nd year	3rd year
Gas meters used for heatings:			
#1234 (In therms)	15,000	18,000	17,000
#2345	10,000	12,000	11,000
Subtotal	25,000	30,000	28,000
Change factor (HUD supplied)	1.05	1.05	1.05
	26,250	31,500	29,400

Example Showing Application of Change Factor—Continued

	Base year		
	1st year	2nd year	3rd year
Gas meters not used for heating: #3456	2,500	2,600	2,650
Total adjusted allowable gas consumption level	28,750	34,100	32,050

No PHA will be required to use a Change Factor of less than 1.00. All Change Factors of less than 1.00 have been rounded to 1.00 in the HUD publication of Change Factors. A PHA with a Change Factor of 1.00 shall, of course, reflect no change. Change Factors are listed by county. If a PHA manages units in more than one county and those counties have different Change Factors, the above calculation shall be done considering the units in each county and each county's assigned Change Factor. If a PHA manages units in an independent city not within the jurisdiction of a county, it shall: (A) If surrounded by one county, use that county's Change Factor; or (B) if surrounded by more than one county, use the average of the Change Factors of the contiguous counties.

(iv) *Continuous use of adjusted Fixed Base Period.* Once the PHA has determined, and HUD has approved, the allowable Utilities Consumption Level for the Fixed Base Period after application of the Change Factor, the adjusted Fixed Base Period consumption will represent the allowable Utilities Consumption Level, excluding New Projects, for PHA Fiscal Years beginning Janauary 1, 1980, and thereafter. This adjusted Fixed Base Period Utilities Consumption Level shall be used by the PHA until it is notified otherwise by HUD, except for New Projects. If a project subsequently becomes a New Project, a calculation of the allowable Utilities Consumption Level for New Projects shall be submitted by the PHA.

(2) *Adjusted consumption for New Projects.*—(i) *Use of Change Factor.* For New Projects, the PHA shall apply the Change Factor to the HUD approved consumption level used for heating.

(ii) *PHA fiscal years affected.* The Change Factor shall be used to compute the allowable Utilities Consumption Level submitted with the Operating Budgets for PHA Fiscal Years beginning January 1, 1980, and thereafter.

(iii) *Application of Change Factor to consumption of New Projects.* The annual allowable Utilities Consumption Level for New Projects, shall be adjusted by applying the Change Factor to the estimated consumption reading of a meter where the utility is used for heating in part or in total. This consumption shall be from a comparable project during the permissible Fixed Based Period. The consumption of utilities not used for heating shall not be adjusted, but the estimated annual consumption based upon data from a comparable project during the permissible Fixed Base Period shall be added to the adjusted consumption.

(iv) *Continuous use of adjusted consumption.* Once the PHA has determined, and HUD has approved, the allowable Utilities Consumption Level for New Projects, after application of the Change Factor, this level will not change and will represent the allowable level, except for additional New Projects. If there are additional New Projects, a recalculation of the allowable Utilities Consumption Level for New Projects shall be submitted by the PHA. This recalculation shall, however, be consistent with comparable consumption of comparable projects during the permissible Fixed Base Period. The Change Factor shall be applied to the recalculated level.

(e) *Utilities Expense Level where consumption data is unavailable.* If a PHA does not obtain the consumption data for the entire Fixed Based Period, either for its own project(s) or by using comparable consumption data as required in paragraph (c)(2) of this section, it shall request HUD Field Office approval to use actual per unit per month (PUM) utility expenses. These expenses shall exclude Utilities Labor and Other Utilities Expenses. The actual PUM utility expenses shall be taken from the year-end Statement of Operating Receipts and Expenditures, Form HUD–52599, for the PHA Fiscal Year ending on December 31, 1975, March 31, 1976, June 30, 1976 or September 30, 1976. No Change Factor shall be applied to actual PUM utility expenses, and subsequent adjustments regarding such utility or utilities will not be approved for a budget year for whch consumption is established based upon said actuals.

(f) *Adjustments.* PHAs shall request adjustments of Utilities Expense Levels in accordance with § 890.110(c), which requires an adjustment based upon a comparison of actual experience to the estimated level. If the actual consumption exceeds the estimated level, HUD would pay 50 percent of the excess and the PHA would pay 50 percent. If consumption is less than the estimated level, HUD would recapture 50 percent of the savings and the PHA would keep 50 percent. One hundred

percent adjustment would be allowed for increases or decreases in utilities cost rates.

3. Section 890.110)c)(3) and (4) are revised to read as follows:

§ 890.110 Requests for adjustment.

* * * * *

(c) * * *

(3) Fifty percent of any decrease in Utilities Expense Level due to decreased consumption will be retained by the PHA; fifty percent will be offset by HUD against subsequent payments of operating subsidy. The 50/50 adjustment is first applicable to utility adjustments submitted for PHA fiscal years ending December 31, 1980, March 31, 1981, June 30, 1981 and September 30, 1981, and thereafter.

(4) An increase in Utilities Expense Level due to increased consumption will be fully funded by residual receipts after provision for reserves, if available; if not available and if the increase would result in a reduction of the operating reserve below the authorized maximum, fifty percent of the amount of the reduction below such maximum will be funded by increased operating subsidy payments, subject to the availability of funds, if such excess utility consumption was due to causes which were beyond the control of the PHA. The 50/50 adjustment is first applicable to utility adjustments submitted for PHA fiscal years ending December 31, 1980, March 31, 1981, June 30, 1981 and September 30, 1981, and thereafter.

* * * * *

(U.S. Housing Act of 1937, 42 U.S.C. 1937 et seq. and sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d))

Issued at Washington, D.C., May 20, 1980.

Lawrence B. Simons,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 80-15988 Filed 5-23-80; 8:45 am]

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Federal Register

Tuesday
May 27, 1980

Part VI

Department of Agriculture

Farmers Home Administration

Economic Emergency Loans

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1945

Economic Emergency Loans

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulation on insured Economic Emergency (EE) loans. This action is required to fully implement the provisions of Pub. L. 96–220, and to incorporate certain changes which were published as Proposed Rules on February 27, 1980. This action is also intended to tighten the "test for credit elsewhere" requirements for applicants and to restrict the use of EE loan funds for refinancing secured and unsecured debts to converse EE loan funds in order to provide EE loan assistance to more farmers who are affected by adverse economic conditions.

DATES: Effective date: These requirements will become effective June 2, 1980. Comments due date: June 26, 1980.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Directives Management Branch, FmHA, USDA, Room 6346–S, Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection at the address given above.

FOR FURTHER INFORMATION CONTACT: Mr. William Krause, USDA, FmHA, Room 5344, South Agriculture Building, 14th and Independence Avenue, SW., Washington, DC 20250. Telephone: (202) 447–6257.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under procedures established in Secretary's Memorandum No. 1955 to implement Executive Order 12044, and has been classified as "significant." The emergency nature of this action warrants publication of this final action without completion of a Final Impact Statement. A Final Impact Statement will be developed after public comments have been received.

Mr. Alex P. Mercure, Assistant Secretary for Rural Development, has determined that an emergency situation exists which warrants publication without opportunity for a public comment period on this final action in order to fully implement the provisions of Pub. L. 96–220 and provide additional EE loan funds immediately to farmers, ranchers, and agriculture operators who are suffering economic stresses due to the general lack of agricultural credit from private and cooperative agricultural credit sources.

Further, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this emergency final action are impracticable and contrary to the public interest; and good cause is found for making this emergency final action effective less than 30 days after publication of this document in the Federal Register. Comments have been solicited for 30 days after publication of this document (June 26, 1980), and this emergency final action will be scheduled for review so that a final document discussing comments received and any amendments required can be published in the Federal Register as soon as possible.

The reporting and recordkeeping requirements contained in this rule have been submitted for approval by the Office of Management and Budget (OMB) in accordance with the Federal Reports Act of 1942. If OMB does not approve, without change, the reporting and recordkeeping requirements contained in this rule, FmHA will revise the rule as necessary to comply with the decision of OMB. FmHA will publish a notice in a future issue of the Federal Register concerning OMB's decision on these requirements.

Various sections of Subpart C of Part 1945, Chapter XVIII, Title 7, Code of Federal Regulations are amended. On March 30, 1980, the President signed Pub. L. 96–220, amending Title II of Pub. L. 95–334 (Emergency Agricultural credit act of 1978). This law provides for the extension of the EE loan program, tightening the "test for credit elsewhere" requirements, restricting the use of EE insured loan funds for refinancing debts, and shortening the waiting period for graduation reviews. In addition to the changes necessitated by this legislation, FmHA is incorporating certain changes which were published in the Federal Register for public comment on February 27, 1980 (45 FR 12827). No comments were received on this proposal.

In addition to these changes, the change to the introductory paragraph of § 1945.112 (b) and the change to § 1945.112 (e) are needed because when they were published as a final rule on December 19, 1979 (44 FR 75104) they contained inadvertent wordings, which, if left unchanged, would contravene the intent of the statutory terms "bona fide farmer" and "character", respectively.

The major changes to Subpart C of Part 1945 are as follows:

1. Section 1945.102 is amended to make certain editorial changes and to replace the term "a local conventional agricultural lender" with "private and cooperative agricultural lenders".

2. Section 1945.104 (a)(4) is amended to expand and clarify the definition of "Aquaculture".

3. Section 1945.105 is amended to tighten the "test for credit elsewhere" requirements for individual and entity type EE loan applicants and to give proper consideration to applicants' "use of nonfarm assets" in determining eligibility for EE loans.

4. Section 1945.112 (b)(1) is amended to allow an individual applicant or the applicant's family members to devote more than 50 percent of their time to agricultural production rather than provide more than 50 percent of the time needed to operate the farm. It is also amended to stipulate the period of time a bona fide farmer must be actually engaged in farming to qualify for an EE loan.

5. Section 1945.112 (c) and (c)(1), (2), (3), and (4) are added to provide for a change in the form of individual and entity type EE loan applicants.

6. Section 1945.112 (e) is amended to merely emphasize repayment ability and reliability when determining an applicant's character.

7. Section 1945.116 (a)(2) is amended to show that only *annual* secured and unsecured family living and farm production debts owed by an applicant to another lender(s) may be considered for partial or full payment. Subparagraphs (i), (ii), and (iii) set forth the limitations that must be taken into consideration before an EE loan can be made to pay such debts.

8. Section 1945.116 (a)(3) is added to permit EE loan funds to be used only to pay, under certain conditions, delinquent installments, plus the next installment owed to another lender(s) and to prohibit the payment of a nondelinquent debt(s) in full or a nondelinquent balloon installment.

9. Section 1945.116 (a)(14) is amended to remove the provision for refinancing unsecured real estate debts.

10. Section 1945.116 (b)(3) is amended to permit, only under certain conditions, the use of EE loan funds for payment of existing delinquent installment(s) plus the next installment owed to another lender(s) on farm real estate or other farm and home debts and to prohibit the use of EE loan funds to pay an applicant's farm real estate or other farm and home debts in full with a nondelinquent installment or to pay a

nondelinquent balloon installment in full.

11. Reference to "total refinancing" of debts has been removed from § 1945.116 (b)(3) (iii) and (iv).

12. Section 1945.117 (a)(5) is amended to remove the reference to "total refinancing" of debts and to show that installment(s) owed on farm or home real estate debts *cannot* be paid with EE loan funds involving real estate purchased and title conveyed to the applicant less than one year before the date of the EE loan application.

13. Section 1945.118 (b)(1)(i) is amended to show the conditions that must be met and documented to justify a 20-year repayment period for an EE loan made for operating purposes.

14. Section 1945.118 (b)(2) is amended to normally restrict the terms of EE loans made for real estate purposes to 30 years and to show the conditions that must be met to justify a 40-year repayment period.

15. Section 1945.120 (b)(7)(iii) is amended to remove the provision for using EE loan funds to refinance a purchase contract(s) which contains any objectionable clause(s) that prohibits the applicant from pledging to FmHA a mortgageable interest in the property.

16. Section 1945.136 is amended to show an initial 3-year and every other year thereafter waiting period for reviewing EE loans for graduation and to provide that the applicants will be advised of graduation requirements during loan processing and at loan closing.

Accordingly, Subpart C of Part 1945 is amended as follows:

PART 1945—EMERGENCY

Subpart C—Economic Emergency Loans

1. Section 1945.102 is amended to read as follows:

§ 1945.102 Program objectives.

The objective of EE loans is to make adequate financial assistance available during the period authorized by Title II of Pub. L. 95–334, as amended, (authority expires September 30, 1981) in the form of loans insured or guaranteed by FmHA for bona fide farmers and ranchers who are primarily and directly engaged in agricultural production so that they may continue their farming or ranching operations during the economic emergency which has caused a lack of agricultural credit due to economic stress such as a general tightening of agricultural credit *or* an unfavorable relationship between production costs and prices received for agricultural commodities. *It is the policy of FmHA to make insured EE loans only when guaranteed EE loans are not available through private and cooperative agricultural lenders.*

2. Section 1945.104(a)(4) is amended to read as follows:

§ 1945.104 Definitions and abbreviations

(a) *Definitions.* * * *

(4) *Aquaculture.* The husbandry of aquatic organisms by an applicant or borrower under a controlled or selected environment. Aquaculture operations are considered to be farming operations. Aquatic organisms may consist of any species of finfish, mollusk, crustacean (or other invertebrate), amphibian, reptile, or aquatic plant. An aquaculture operation is considered to be a farm only if it is conducted on grounds which the applicant owns, leases, or has an exclusive right to use. An exclusive right to use must be evidenced by a permit issued to the applicant and the permit must specifically identify the waters available to be used by the applicant only.

* * * * *

3. Section 1945.105 is amended to read as follows:

§ 1945.105 Credit elsewhere.

(a) *Test for credit for individuals and entities.* The applicant must be unable to obtain sufficient credit elsewhere to finance actual needs at reasonable rates and terms, taking into consideration prevailing private and cooperative rates and terms in the community in or near which the applicant resides for loans for similar purposes and periods of time. If the applicant has been getting credit away from the local community where the farming operation is located, that source of credit must also be considered. The applicant's equity in *all assets,* including but not limited to real estate, chattels, stocks, bonds, and Certificates of Deposit will be considered in determining ability to obtain such credit from other sources. Also, the applicant must offer to pledge *all assets* as security when requesting credit from other lenders. Cooperatives, corporations, and partnerships and the principal members, principal stockholders, and principal partners, both individually and collectively, must be unable to obtain the required funds with their own resources or with credit obtained from other sources. Form FmHA 1940–38, "Request for Lender's Verification of Loan Application," when appropriate, must be filed in the County Office case folders and any additional facts concerning the findings in all cases must be documented and recorded in the running record.

(b) *Test for credit certification requirements.* The applicant shall certify in writing on the application form and the County Supervisor *shall* determine that adequate credit elsewhere is not available to finance the applicant's actual needs.

(1) If the EE loan(s) requested is less than $300,000, the following actions will be taken:

(i) When it appears from a review of the application that it would be unduly burdensome to require the applicant to obtain written declinations of credit from other lenders, the County Supervisor may make an exception to this requirement, provided the County Supervisor knows the other lenders' programs well enough to determine that no possibility exists for the applicant to obtain the credit needed from these lenders. This conclusion and the basis for it will be recorded in the running record and further checks will not be necessary. However, the applicant's normal lender(s) *must be contacted in all cases* and the findings will be recorded in the running record.

(ii) If the County Supervisor questions whether the applicant is unable to obtain the credit needed from other agricultural lenders in the area, such lenders will be contacted. Form FmHA 1940–38 must be completed by all lenders contacted and returned to the county office. In lieu of using Form FmHA 1940–38, the lenders may submit a letter stating whether they will extend the credit needed by the applicant. If one or more of the lending sources contacted will provide the applicant with sufficient credit to finance actual needs at reasonable rates and terms taking into consideration prevailing private and cooperative rates and terms in the community, the applicant will be advised that it is not eligible for an EE loan. If the applicant cannot qualify for the needed credit from the lenders contacted, but one or more of them have indicated they would provide credit with an FmHA guarantee, the applicant will be advised to file an application with that lender(s) so that a guaranteed EE loan request can be processed by the lender for consideration by FmHA. If the County Supervisor believes it necessary, the action required in paragraph (b)(2) of this section can be taken.

(iii) When the County Supervisor receives letters or other written evidence including Form FmHA 1940–38 from a lender(s) indicating that the applicant is unable to obtain satisfactory credit, this will be included in the loan docket. Such evidence will not preclude the County Supervisor from contacting other farm lenders in the area and making an independent

determination of the applicant's ability to obtain credit elsewhere.

(2) If the EE loan(s) request is $300,000 or more, the following actions will be taken:

(i) The applicant will be required to apply at not less than three conventional lending sources, including the Production Credit Association or Federal Land Bank, as appropriate, in the local community. However, when an applicant has a net worth of $1 million or more but cannot obtain credit in the local community, the applicant will be required to contact at least two other lending sources out of the local area. One or more of the lenders contacted must be the applicant's normal lender(s) even though the lender is not located in the local community.

(ii) Form FmHA 1940–38 must be completed by all lending sources contacted and returned to the County Office. If one or more of the lending sources contacted will provide the applicant with sufficient credit to finance actual needs at reasonable rates and terms taking into consideration prevailing private and cooperative rates and terms in the community, the applicant will be advised that it is not eligible for an EE loan. If the applicant cannot qualify for the needed credit from the lenders contacted, but one or more of them have indicated they would provide the credit with an FmHA guarantee, the applicant will be advised to file an application with that lender(s) so that a guaranteed EE loan request can be processed by the lender for consideration by FmHA. Only if the applicant is not able to obtain a loan—either with or without an FmHA guarantee—from one or more of the lending sources contacted, will the applicant be considered for an insured EE loan.

(iii) When the County Supervisor receives Forms FmHA 1940–38 indicating that the applicant is unable to obtain satisfactory credit, the forms will be placed in the loan docket. However, such evidence will not preclude the County Supervisor from contacting other farm lenders in the area and making an independent determination of the applicant's ability to obtain credit elsewhere.

(c) *Use of nonfarm assets.* The basic objective of EE loans is, through financial assistance, to enable eligible *farmers* to maintain a viable *farming operation* after they have sustained substantial economic losses. Therefore, since the goal of EE loans is maintaining a sound *farm* economy, applicants with large holdings in nonfarm assets not essential to the successful operation of their *farm* will offer those assets as security for loans requested from other lenders.

(1) If other lenders will not provide the needed credit even with these assets offered as security for the loans, an EE loan may be considered provided it is determined that:

(i) The applicant by selling all or a part of the *nonfarm* assets could not meet the total financial needs of the farm *without other credit;* or

(ii) The applicant by selling all or a part of the *nonfarm* assets could not meet the total financial needs of the farm *with credit from other sources.*

(2) When an EE loan will be made, after other lenders have declined to provide credit, the County Supervisor may still require the applicant to sell all or a part of such assets to meet a portion of the applicant's needs in connection with processing an EE loan for the difference between the applicant's actual needs and the amount realized by the sale of the assets. If the applicant cannot sell the assets before the loan is closed, the applicant will mortgage such assets to FmHA and agree in writing, in a manner approved by OGC, to sell them within a one year period and apply the proceeds to reduce the EE debt.

4. Section 1945.112 (c), (d), (e), (f) and (g) are renumbered to (d), (e), (f), (g), and (h) respectively without change.

In § 1945.112, the introductory paragraph of (b), (b)(1) and (e) are revised and a new paragraph (c) is added to read as follows:

§ 1945.112 Eligibility.

* * * * *

(b) *Bona fide farmer.* Be a *bona fide* farmer (owner-operator or tenant-operator), doing business in the United States either as an individual, cooperative, corporation, or partnership, that is recognized in the community as one primarily and directly engaged in agricultural production. *In the case of an individual loan applicant,* the term "primarily and directly engaged in agricultural production" means that the applicant(s) derives more than 50 percent of the gross income from the applicant's own agricultural production *or* either the applicant or family members of the applicant devote more than 50 percent of their time to such agricultural production. *In the case of a cooperative, corporation, or partnership loan applicant,* the term "primarily and directly engaged in agricultural production" means that the cooperative, corporation, or partnership derives more than 50 percent of its gross income from agricultural production *and* the member(s), shareholder(s), or partner(s) owning or controlling a majority interest in such cooperative, corporation or partnership either derive more than 50 percent of their gross income from their own or the cooperative's, corporation's, or partnership's agricultural production, *or* devote more than 50 percent of their time to such agricultural production.

(1) A bona fide farmer must be actually engaged in farming operations to be financed by an EE loan, and must have been engaged in farming during the 12-month period, or one full production and marketing cycle, whichever is the lesser, immediately preceding the date of the application. If the applicant is an individual, the applicant must manage such farming operation. If the applicant is a cooperative, corporation, or partnership, it must be managed by one or more of the members, stockholders, or partners. One who does not devote full time to the farming enterprise may be considered the manager provided the person visits the farm at sufficiently frequent intervals to exercise control over the farming enterprise, gives directions as to how it should be run, and sees that the enterprise is being carried on properly. Any enterprise that involves an outside full-time manager or management service does not qualify regardless of the number of visits made. In addition, as between two applications on file at the same time, FmHA will give preference to an applicant who owns and operates not larger than a family farm as defined in § 1945.104(a)(11). However, for purposes of an EE loan, this does not exclude an applicant who does not own or operate a family farm.

* * * * *

(c) *Change in the form of an applicant.* A change in the form of an applicant from an individual, partnership, cooperative, or corporation to another form of legal entity will not disqualify the new entity if it is conducting the same operation as was conducted during the 12-month period, or during one full production and marketing cycle, whichever is the lesser, immediately preceding the date of the application, and is primarily owned by substantially the same people that owned the operation during the 12-month period, or during one full production and marketing cycle, whichever is the lesser, immediately preceding the date of the application.

(1) When one or more *individuals* who were engaged in a farming operation during the 12-month period, or during one full production and marketing cycle, whichever is the lesser, immediately preceding the application later forms a partnership, cooperative, or corporation, the operation's application may still receive consideration provided such individual(s) owns at least 50 percent of

the new partnership assets or cooperative or corporation's voting stock and continues to manage or control the farming operation.

(2) When a *partnership* that was engaged in a farming operation during the 12-month period, or during one full production and marketing cycle, whichever is the lesser, immediately preceding the application later dissolves and the operation is continued by an individual or a newly formed partnership, cooperative, or corporation, an application from the individual or the new entity will receive consideration provided one or more of the partners who managed the farming operation for the prior partnership will now manage the operation for the applicant, and provided:

(i) The assets of the prior partnership are now owned by an individual applicant who, as a partner in the prior partnership, had owned at least 50 percent of the partnership assets; or

(ii) The assets of the prior partnership are now owned by a new partnership applicant and the partners who had owned at least 50 percent of the assets of the prior partnership are now partners owning at least 50 percent of the assets of the new partnership applicant; or

(iii) The assets of the prior partnership are now owned by a new cooperative or corporation applicant, and the partners of the prior partnership who owned at least 50 percent of those assets now own at least 50 percent of the voting stock of the new cooperative or corporation applicant.

(3) When a *cooperative* that was engaged in a farming operation during the 12-month period, or during one full production and marketing cycle, whichever is the lesser, immediately preceding the application dissolves but the farming operation is continued by an individual or a newly formed cooperative, corporation, or partnership, the application from the individual or new entity will receive consideration provided one or more of the members who managed the farming operation for the prior cooperative must now manage the operation for the new applicant, and provided:

(i) The assets of the dissolved cooperative are now owned by an individual who had owned at least 50 percent of the voting stock of the former cooperative, or

(ii) The assets of the former cooperative are now owned by a new partnership applicant and the members who had owned at least 50 percent of that cooperative are now partners owning at least 50 percent of the assets of the new partnership applicant, or

(iii) The assets of the former cooperative are now owned by a new cooperative or corporation applicant and the members or stockholders who had owned at least 50 percent of the voting stock of the former cooperative are now members or stockholders owning at least 50 percent of the voting stock of the new cooperative or corporation applicant.

(4) When a *corporation* that was engaged in a farming operation during the 12-month period, or during one full production and marketing cycle, whichever is the lesser, immediately preceding the application dissolves but the farming operation is continued by an individual or newly formed cooperative, corporation, or partnership, the application from the individual or new entity will receive consideration provided one or more of the stockholders who managed the farming operation for the prior corporation must now manage the operation for the new applicant, and provided:

(i) The assets of the dissolved corporation are now owned by an individual who had owned at least 50 percent of the voting stock of the former corporation, or

(ii) The assets of the former corporation are now owned by a new partnership applicant and the stockholders who had owned at least 50 percent of that corporation are now partners owning at least 50 percent of the assets of the new partnership applicant, or

(iii) The assets of the former corporation are now owned by a new cooperative or corporation applicant and the members or stockholders who had owned at least 50 percent of the voting stock of the former corporation are now members or stockholders owning at least 50 percent of the voting stock of the new cooperative or corporation applicant.

* * * * *

(e) *Character, industry, training, or experience and ability.* Possess the character (emphasizing repayment ability and reliability), industry, training and/or experience and ability necessary to carry out the proposed operations and honestly endeavor to carry out the undertakings and obligations in connection with the loan.

* * * * *

5. Section 1945.116 (a)(3) through (a)(14) are renumbered to (a)(4) through (a)(15) respectively. § 1945.116 (a)(2); (a)(14) which has been renumbered from (a)(13); and (b)(3) are amended and § 1945.116 (a)(3) is added to read as follows:

§ 1945.116 Loan purposes.

(a) *Operating purposes.* * * *

(2) Payment of secured or unsecured *annual* family living and farm production debts (*not* including FmHA insured and guranteed loans) when it is determined that the lender(s) is demanding payment in full and will not continue with the applicant or carry a portion of the applicant's debt(s).

(i) Preference will be given to paying those debts that will be most helpful to the applicant in carrying on essential farm and home operations.

(ii) Ordinarily, in the case of old unsecured debts or inadequately secured debts, the applicant will be requested to contact the applicant's creditor(s) and attempt to obtain a substantial reduction of such debts before the payment of such debts with EE loan funds.

(iii) When *annual* credit advances were made for family living and/or farm production expenses, but also included funds for capital expenditures such as equipment, foundation livestock, and real estate purchases or improvements, *only* that portion advanced for family living and farm production expenses may be *fully* paid with EE loan funds. However, either one year's interest and an amount not to exceed 20 percent of the appraised market value of the essential farm and home equipment and livestock under prior lien to the creditor(s), *or* 20 percent of the balance owed to the creditor(s) (whichever is the lesser) may be paid with EE loan funds.

(3) Payment of existing delinquent installment(s) plus the next installment owed on farm and home operating debts which were amortized over a period of more than one year (*not* including FmHA insured and guaranteed loans) when it is determined that the lender(s) is demanding payment of the delinquent installment(s) and will not continue with the applicant without receiving payment of such installment(s). When a nondelinquent installment is involved, payment of a nondelinquent installment may be made *only* if the applicant has insufficient cash flow to meet the existing payment terms and the indebtedness will *not* be paid in full with such payment. When the "nondelinquent" installment is a balloon payment, such installment will *not* be paid in full. In such cases, only an amount equal to a regular installment will be paid and the lender will be required to extend the remaining portion of the balloon payment for a reasonable period of time.

* * * * *

(14) Up to $25,000 in a fiscal year for real estate improvements or repairs. The

following determinations must first be made:

* * * * *

(b) *Real estate purposes.* * * *

(3) Payment of existing delinquent installment(s) plus the next installment owed on farm real estate or other farm and home debts (*not* including FmHA insured and guaranteed loans) when it is determined that the lender(s) is demanding payment of the delinquent installment(s) and will not continue with the applicant without receiving payment of such installment(s). When a nondelinquent installment is involved, the following conditions must be met:

(i) Payment of a nondelinquent installment may be made *only* if the applicant has insufficient cash flow to meet the existing payment terms and the indebtedness will *not* be paid in full with such payment. When the "non-delinquent" installment is a balloon payment, such installment will *not* be paid in full. In such cases, only an amount equal to a regular installment will be paid and the lender will be required to extend the remaining portion of the balloon payment for a reasonable period of time.

(ii) The limitation found in § 1945.117(a)(5) must be complied with.

(iii) Preference will be given to paying those installments that will be most helpful to the applicant in carrying on essential farm and home operations.

(iv) Ordinarily, in the case of old unsecured debts or inadequately secured debts, the applicant will be requested to contact the applicant's creditor(s) and attempt to obtain a substantial reduction of such debts before payment of installments.

* * * * *

6. § 1945.117(a)(5) is amended to read as follows:

§ 1945.117 Loan limitations and special provisions.

(a) *Limitations on use of loan funds.* * * *

(5) Installments owed on farm or home real estate debts will not be paid unless such real estate was purchased and title conveyed to the applicant at least one year before the date of the EE loan application.

* * * * *

7. § 1945.118 (b)(1)(i) and (b)(2) are amended to read as follows:

§ 1945.118 Loan rates and terms.

* * * * *

(b) *Terms of loan repayment.* * * *

(1) * * *

(i) Loans will be for a period not to exceed 7 years. Loans may be scheduled for a longer repayment period if the FmHA approval official determines that the needs of the applicant justify a longer repayment period. Such period may be approved as warranted but cannot exceed 20 years. Generally, real estate will be needed as security when the longer repayment period is authorized. This longer repayment period will only be used when the applicant would be unable to repay the loan in a shorter period taking into consideration rescheduling possibilities. The reasons the longer period is given must be documented in the county office case file.

* * * * *

(2) Loans for real estate and items financed under § 1945.116(b) (*real estate purposes*) will normally be scheduled for repayment in *not more than 30 years.* Loans may be scheduled for a longer repayment period if the FmHA approval official determines that the needs of the applicant justify a longer repayment period. Such period may be approved as warranted but cannot exceed 40 years. The longer repayment period will only be used when the applicant would be unable to repay the loan in a shorter period. The reasons the longer period is given must be documented in the county office case file.

8. § 1945.120(b)(7)(iii) is amended to read as follows:

§ 1945.120 Collateral requirements.

* * * * *

(b) *Additional requirements.* * * *

(7) * * *

* * * * *

(iii) If a satisfactory contract of sale cannot be renegotiated or the purchase contract holder refuses to enter into the agreement described in paragraph (b)(7)(ii) of this section, the applicant will make every effort to refinance the existing purchase contract.

* * * * *

9. § 1945.136 is amended to read as follows:

§ 1945.136 Graduation.

Borrowers will be required to graduate when FmHA determines they are able to obtain their needed credit from conventional sources. All borrowers will be advised that their loans will be reviewed for graduation by FmHA. Applicants will also be advised during loan processing and again at loan closing that they will be required to refinance at any time if other satisfactory credit is available to them even though their loans have not fully matured. This will be in accordance with the graduation procedure set forth in Part 1865 of this Chapter (FmHA Instruction 451.6). EE loans will be reviewed three years after they are made and every other year thereafter.

* * * * *

This document has been reviewed in accordance with 7 CFR Part 1901, Subpart G, "Environmental Impact Statements." It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91-190, an Environmental Impact Statement is not required.

(7 U.S.C. 1989; 5 U.S.C. 301; Title II of Pub. L. 95-334, as amended by Pub. L. 96-220; delegation of authority by the Secretary of Agriculture 7 CFR 2.23; delegation of authority by the Assistant Secretary for Rural Development, 7 CFR 2.70)

Dated: May 16, 1980.

Alex P. Mercure,

Assistant Secretary for Rural Development.

[FR Doc. 80-15994 Filed 5-23-80; 8:45 am]

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Part VII

Department of Energy

Office of the Secretary

Emergency Building Temperature Restrictions

DEPARTMENT OF ENERGY

Office of the Secretary

10 CFR Part 490

[Docket No. CAS-RM-79-110]

Emergency Building Temperature Restrictions; Amendment of Regulations

AGENCY: Department of Energy.

ACTION: Notice of proposed rulemaking and public hearings.

SUMMARY: Under the authority of the Energy Policy and Conservation Act (42 U.S.C. 6201) (EPCA), Executive Order 11912 (41 FR 15825, April 13, 1976) and the "Standby Conservation Plan No. 2: Emergency Building Temperature Restrictions" (44 FR 12906, March 8, 1979), the Department of Energy is amending the Emergency Building Temperature Restrictions (EBTR) regulations (44 FR 39354, July 5, 1979) which became effective on July 16, 1979 (44 FR 40629, July 12, 1979 and 44 FR 41205, July 16, 1979) and were extended on April 15, 1980 (45 FR 26019, April 17, 1980).

The regulations place restrictions on the thermostat settings for heating, cooling, and hot water in commercial, industrial, and other nonresidential buildings to reduce energy consumption.

These amendments are intended to improve the operation of the program based on experiences to date. The specific changes and rationale are set forth below in the supplementary information section.

DATES: Written comments must be received by June 26, 1980 at 4:30 p.m., eastern time in order to ensure their consideration. A public hearing will be held in Washington, D.C. (June 12, 1980) at 9:30 a.m. local time. Requests to speak at the public hearing should be received by June 5, 1980. Speakers will be notified of their selection on June 9, 1980. One hundred copies of oral statements are due by June 11, 1980.

ADDRESSES: Comments should be addressed to Dorothy Hamid, Public Hearings Management, Department of Energy, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461, telephone (202) 653-3757.

A public hearing will be held on these amendments at Room 2105, 2000 M Street, N.W., Washington, D.C.

Please direct requests to speak to: Dorothy Hamid, Public Hearings Management, Department of Energy, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461, Telephone: 202-653-3757.

FOR FURTHER INFORMATION CONTACT:

W. Lorn Harvey or Jan Marfyak, Office of Emergency Conservation Programs, Conservation and Solar Energy, Department of Energy, 1000 Independence Avenue, S.W., Room GE-004A, Washington, D.C. 20585. Telephone (202) 252-4966.

Edward H. Pulliam, Office of General Counsel, Department of Energy, 1000 Independence Avenue, S.W., Room 1E-258, Washington, D.C. 20585. Telephone (202) 252-9507.

Emergency Conservation Service Hotline, (800) 424-9122 from the continental U.S., (800) 424-9088 from Alaska, Hawaii, Puerto Rico, and the Virgin Islands, (202) 252-4950 from metropolitan Washington, D.C.

SUPPLEMENTARY INFORMATION: Standby Federal Conservation Plan No. 2, Emergency Building Temperature Restrictions (the Plan) was submitted to and approved by Congress pursuant to Section 201 of the Energy Policy and Conservation Act (42 U.S.C. 6201) which authorized the President to develop energy conservation contingency plans. Emergency Building Temperature Restrictions (EBTR) final regulations (the Regulations) were published by the Department of Energy (DOE) on July 5, 1979 (44 FR 39354) and became effective by President Proclamation on July 16, 1979 (44 FR 40629, July 12, 1979 and 44 FR 41205, July 16, 1979). The President issued a proclamation on April 15, 1980 (45 FR 26019, April 17, 1980) continuing EBTR in effect until January 16, 1981, unless earlier rescinded.

Throughout the effective period of the Regulations, DOE has continued to receive public input on these temperature restrictions, including over 57,000 telephone calls on the Emergency Conservation Service Hotline, over 400,000 pieces of mail, and comment from trade and professional organizations as well as Federal agencies. The amendments presented in this notice reflect this input and the experience of DOE over the course of the EBTR program. The most significant amendment is a provision allowing building owners and operators to claim exemptions on the basis of comparable energy saving plans.

Alternate Plans by Building Owners or Operators

The Regulations have been amended (§ 490.36) to provide an exemption to building owners and operators implementing an alternate plan designed to conserve as much energy as would be conserved by strict compliance with the temperature restrictions set forth in the Regulations. The exemption is only partial, in that the owner or operator must maintain temperature limits of 68 degrees when heating, and 74 degrees when cooling as compared with the 65/78 degree limits prescribed by the Regulations. In conjunction with these less stringent temperature limits the building owner or operator must institute other energy conservation measures which will conserve as much energy as would be conserved by strict compliance with the temperature restrictions as set forth in Subparts B and C of the Regulations. Alternate means are not restricted to adjustments in heating, ventilating and air-conditioning (HVAC) system operation, but may include changes in the design, construction or operation of a building, such as lighting reduction, insulation, weatherstripping, installation of control systems or changed hours of operation.

Like other exemptions to these Regulations, this exemption is self-certifying. Alternate plans need not be approved by DOE, although the individual claiming the exemption will be required to present proof of equivalent savings if requested by a State or Federal inspector. Such proof must include, but is not limited to, the most current utility/fuel consumption data available at the time of the inspection, and data for the corresponding period for the previous two years.

This exemption shall not be available in jurisdictions which have had plans approved under § 490.35 unless the approved plan allows such an exemption.

This amendment is designed to provide maximum flexibility to building owners/operators, and is modeled on the New Jersey "alternate plan" submitted to and approved by DOE for that State under § 490.35 of the Regulations. The plan also affords an opportunity to retailers, restaurateurs and others who have indicated that conservation strategies other than temperature restrictions are more appropriate to their particular circumstances.

A number of trade associations, such as the Building Owners and Managers Association International (BOMA) and the National Resturant Association, have either submitted or intend to submit to DOE, industrywide alternate plans. DOE encourages the use of such plans as guidelines for building owners/operators, as long as their adoption would meet the requirements of this amendment. DOE cannot approve such plans due to the impossibility of certifying that a generic plan would, in all cases, meet the requirements of the exemption. Additionally, the potential administrative burden and cost of reviewing and approving numerous

alternate plans would be excessive, considering the limited life of the EBTR program.

490.5 Definitions.

The following new definitions or revised definitions have been included as amendments in order to clarify the intent of the Regulations.

The definition of "capability for simultaneous heating and cooling" has been further refined by the addition of the words "at the same time," to specify a single HVAC system which may both heat and cool at the same time.

"Coolant" has been defined to specify "the liquid which is circulated through heat exchangers for the purpose of removing heat from the air." Section 490.12 was originally written visualizing chilled water as the coolant. Questions have arisen as to whether Section 490.12 is applicable when the refrigerant itself is the coolant. This modification makes clear that this Section does apply to such refrigerant systems. In a small number of cases, operation of such systems at a coolant temperature of 55 degrees may create the likelihood of compressor damage. An amendment to section 490.12 permits an exemption where such likelihood exists.

"Hospital and health care facility" has been redefined to clarify DOE's intent to include doctors' and dentists' offices within the scope of the regulations, unless an exemption is claimed by the doctor or dentist in order to protect the health of patients.

"Dry-bulb temperature" has been redefined to include "adjusted dry-bulb temperature" as defined in the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 55–74, *"(Thermal Environmental Conditions for Human Occupancy.* This has been done to reduce the chance that an individual will be required by the Regulations to work under conditions thermally less comfortable than those contemplated by the regulations. For example, on a cold day, an individual located next to a large window or exterior wall may sense temperatures below actual room temperature. Adjusted dry-bulb temperature takes into account the effects of unusual radiant heat gain or loss, and air velocity. Since some building owners may wish to avoid the calculations necessary to determine adjusted dry-bulb temperature, another alternative is offered: to take the temperature reading with a globe thermometer.

The definition of "elementary school" has been expanded to include other areas where children of elementary school age congregate. This modification was made since small children may not always be relied upon to adjust their dress habits to suit prevailing indoor temperatures.

"Energy that would otherwise be wasted" has been defined in order to clarify that term as used in Section 490.18.

A definition has been added for "intermediate season" since it is necessary to describe those times when both heating and cooling are required in a building at different times during the same day (e.g., heating in the morning and cooling in the afternoon). "Intermediate season" also refers to those periods when heating and cooling are required at the same time in different parts of the building. This may be the case, for example, in a large office building which, in winter, may require heating near the perimeter due to radiant heat loss, but cooling in the interior rooms due to core heat buildup.

"Reheat" has been defined to clarify the type of system operation proscribed by the Regulations.

"Solar energy" has been redefined to specify the types of renewable resources intended to be encompassed by the term. These include wind, geothermal, small scale water power or biomass, including wood and any combustible municipal or industrial trash or waste materials.

The definition for "unoccupied period" has been refined to specify that a building must be unoccupied for eight hours or more to be considered "unoccupied" for purposes of these Regulations.

A definition has been added for "work station" as that area within a room where an employee ordinarily performs principal work-related tasks. This new definition was necessitated by changes in allowable temperature measurement techniques. This definition is meant to apply to primary work areas (e.g. typist's desk, factory bench) and not to any area of a room where tasks may be occasionally performed.

§ 490.12 HVAC Systems with capability for simultaneous heating and cooling.

This section has been amended to distinguish between the types of systems referred to in § 490.12(b)(1) (fan coil, induction, baseboard or similarly operated units) and those referred to in § 490.12(d)(1) ("all air" systems). Fan coil, induction, baseboard or similarly operated units are those in which cooling or heating of the air in the room is accomplished by passing room air over a heat exchanger in the room to which water or another fluid has been piped. In an all air system, air which had previously been heated or cooled elsewhere in the system is carried into the room through ducts.

Section 490.12 has also been amended to state definitively that the use of reheat is banned by these regulations unless a licensed Professional Engineer determines that adequate temperature control (temperatures between 65° and 78°) cannot be maintained without reheat. Test modeling of various building types with different HVAC systems at Argonne National Laboratory demonstrated that reheat systems, operating with reheat coils on, are the most inefficient HVAC systems. Such systems may be made relatively efficient by turning off reheat coils, with the result of substantial energy savings.

Wording has also been added to this section which specifies DOE's intent to require raising coolant temperatures only to that level at which the HVAC system can function without damage. DOE has received reports that in a small number of systems, compressor surging could result from raising coolant temperatures to those required by the Regulations. Where any doubt exists that equipment will operate satisfactorily at specified coolant temperatures, DOE recommends consultation with the compressor manufacturer.

Section 490.12 has been further revised to clarify proper HVAC operation during the intermediate season. The effect of this revision is to confirm that in the intermediate season a "deadband" between 65° and 78° exists in which no heating or cooling may be supplied to a room except to the extent that temperatures below 78° can be attained with 55° coolant temperatures or 60° supply air, as stipulated in § 490.12. This is not intended to preclude system operation at any time under exemptions available in Section 490.18, including the use of outside air.

§ 490.13 Requirement for accuracy of space-conditioning control devices.

In order to prevent the relocation of thermostats to thwart the intent of these Regulations, an amendment prohibiting such relocation has been added. With this revision, it would be contrary to the Regulations to move a room thermostat from an interior to an exterior wall, or from an occupied room to a storage area in the same thermostat zone, with the intent of thereby raising or lowering temperatures in the occupied room.

This section has been further revised to require that space-conditioning control devices be maintained in proper repair, if such devices are being used to maintain temperatures required by these Regulations.

§ 490.14 Regulation of building temperatures during unoccupied periods.

A number of buildings utilizing heat pump systems have experienced increased energy usage or electric utility bills by complying with EBTR night setback requirements due to an inability to bring building temperatures back up to occupied period temperatures without the use of electrical resistance coils. Use of such coils increases energy consumption and adds to the building's electrical peak load. An amendment has therefore been added which exempts such systems from 55° night setbacks and raises the setback level for those systems to 60° if such operation will reduce monthly energy consumption or peak load use.

§ 490.15 Auxiliary heaters.

The Regulations have been amended to make clear that the use of auxiliary heaters is precluded, except where necessary to bring the temperature in a room or a work station (e.g., desk, work bench) up to 65°. No auxiliary heaters may be used to bring the temperature at a work station above 65°, except where permitted by an exemption or exception. Electric foot warmers and similar devices are not specifically proscribed by the Regulations unless their use brings the room temperature above 65 degrees. Care should always be taken to keep flammable materials away from auxiliary heaters or other electrical devices when in use.

§ 490.17 Measurement techniques.

Allowable measurement techniques have been modified to allow temperature measurement at an average of representative work stations (see definitions, § 490.5) in the room. The nature of some HVAC systems, room size, or demands of business may make the temperature at work stations widely disparate from the average room temperature. When rebalancing the system or relocating the work station is not feasible, room temperatures may be measured by averaging the temperatures at representative work areas in the room. This will afford some relief to individuals at those work stations. The building owner/operator may choose the measuring technique to be used.

In addition, temperature measurement techniques have been expanded to specify meaurement at "breathing level." Breathing level can generally be assumed to be between 4 and 6 feet above the floor.

The Regulations have also been amended to require that HVAC systems be properly balanced. System balancing in accordance with good commercial practice for the applicable HVAC system is crucial if the full energy saving potential of EBTR is to be realized.

§ 490.18 Exemptions from heating and cooling restrictions.

This section has been amended to exempt systems utilizing cold well water for cooling, when cold well water is the only source of cooling energy.

§ 490.31 General exemptions.

Aside from the exemption granted to building owners or operators implementing an alternative plan approved by the Secretary, three other exemptions have been added to the Regulations.

Senior citizen centers providing nutritional, recreational and other facilities specifically intended for use by senior citizens have been exempted from compliance with the Regulations during those times and in those areas where senior citizen activity is conducted. This amendment incorporates a class exception from the Regulations previously granted by the DOE Office of Hearings and Appeals to such facilities. The National Institutes of Health has recommended that temperatures be maintained no lower than 70°F. for the elderly in their residences, particularly the infirm.

An amendment has been included exempting school and workplace shower and changing rooms from heating limit requirements where showers are considered a required part of customary work procedure. The purpose of this amendment is to exempt workplace shower and changing areas in cases where exposure of workers to potentially dangerous or irritating substances such as coal or other mining dust, toxic chemicals, excessive grime, etc., would make it impractical or unhealthy for workers to leave the workplace before showering. This amendment is not intended to exempt shower and changing rooms in gymasia, health clubs or similar establishments, where showers on the premises are optional.

An amendment has also been added which exempts individuals from coverage by the Regulations who are required by security, safety or health codes to wear special or protective clothing to perform manufacturing or industrial processes, when temperatures prescribed in the regulations would pose a danger to their health. For example, this exemption would cover areas where individuals are required to wear impermeable coveralls due to possible exposure to fiberglass, radiation, fine dust, spray paints etc. In other instances, high security or safety risks exist that prevent individuals from wearing needed layers of clothing to retain warmth (e.g. U.S. mints, activities where there are high risks of clothing being caught in machinery).

§ 490.34 Scope of exceptions or exemptions.

This section has been amended to require building owners or operators to provide temperature levels consistent with the needs of the exempted or excepted building area, business, system or individual. Such a requirement was found to be necessary to insure that building owners and operators fulfill their obligations to tenants and employees. Such adjustments must be made, to the extent practicable, in a manner consistent with maximum energy savings. For example, it may be more energy efficient to provide one individual granted an exception with a space heater than to adjust an entire HVAC zone to the temperature permitted by the exception.

Nothing in these Regulations is intended to imply that DOE requires temperatures above 78° for heating or below 65° for cooling.

Comment Procedures

A 30-day public comment period on these amendments to the EBTR Regulations begins with publication of this notice. A comment period of only 30 days is hereby chosen in lieu of the normal 60 day comment period required by Executive Order 12044 since it is imperative that these Regulations, should they be published as a final Rulemaking, are in place for the summer cooling season. It is expected that amendment of these regulations will help minimize discomfort during the heating and cooling seasons, and that the earliest possible adoption of these changes will be in the public interest. The public is invited to send written comments to the addresses indicated in the "ADDRESSES" section of this notice. Such comments should be identified on the outside envelope and on documents submitted with the designation "Emergency Building Temperature Restrictions—Amendments." Fifteeen copies, if possible, would be appreciated. All comments received will be available for public inspection in the DOE Reading Room, Room 5B180, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Comments should be received 30 days from publication in the Federal Register, in order to be considered. Any information or data you consider to be

confidential must be so identified. DOE reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

Public Hearing

A public hearing will be held on these amendments on June 12, 1980, beginning at 9:30 a.m. local time at Room 2105, M Street, NW., Washington, D.C. Requests to speak at the public hearing should be received by June 5, 1980. Speakers will be notified of their selection on June 9, 1980. One hundred copies of oral statments are due by June 11, 1980. Please direct requests to speak to: Dorothy Hamid, Public Hearings Management, Department of Energy, Room 2313, 2000 M Street, NW., Washington, D.C. 20461. Telephone: 202–653–3757.

In consideration of the foregoing, chapter II of title 10 of the Code of Federal Regulations is amended as set forth below. Issued in Washington, D.C., on May 21, 1980.

Worth Bateman,

Acting Secretary, Department of Energy.

Authority: Federal Energy Administration Act of 1974, 15 U.S.C. 761 *et seq.;* Energy Policy and Conservation Act, 42 U.S.C. 6201 *et seq.;* Department of Energy Organization Act, 42 U.S.C. 7101 *et seq.;* E.O. 11790, 39 FR 23185 (June 27, 1974); E.O. 12009, 42 FR 4627 (September 15, 1977); Standby Conservation Plan No. 2, Emergency Building Temperature Restrictions, 44 FR 12906 (March 8, 1979); E.O. 11912, 41 FR 15825 (April 13, 1976); Presidential Proclamation No. 4667, 44 FR 40629 (July 12, 1979); and Presidential Proclamation No. 4750, 45 FR 26019 (April 17, 1980)

PART 490—EMERGENCY BUILDING TEMPERATURE RESTRICTIONS

10 CFR Part 490 is amended as follows:

1. Section 490.5(a) is amended by inserting the words "at the same time" between the words "while" and "supplying."

§ 490.5 Definitions.

2. Section 490.5(g) is revised to read as follows:

(g) "Dry-bulb temperature" means the temperature of air as measured by a dry-bulb, or ordinary thermometer which directly measures air temperature. Where unusual radiant heat gain or loss, or where unusually high air velocity conditions prevail, an adjusted dry-bulb temperature may be calculated in accordance with American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 55–74 *Thermal Environmental Conditions for Human Occupancy.* Alternatively, temperature may be read directly using a Vernon-type globe thermometer.

3. Section 490.5(h) is revised to read as follows:

(h) "Elementary school" means any school which has any grades kindergarten through sixth grade, or any other building or portion thereof which houses schools, clubs, and organizations whose membership is open to and composed exclusively of children in grades six and below only during the time when this facility is being used by children in these grades: Provided, that if the non-elementary grade portions of a building have space-conditioning control devices separate from the elementary portions, the non-elementary grade portions are not included within the definition of elementary school.

4. Section 490.5(n) is amended by adding at the end of the sentence, "but does not include the offices of physicians, dentists and other members of health care professions licensed by the state to provide health related services."

5. Section 490.5(y) is revised to read as follows:

(y) "Solar Energy" means energy derived from the sun directly through the solar heating of air, water and other fluids; indirectly through the use of electricity produced by solar photovoltaic or solar thermal processes; or indirectly through the use of wind, geothermal, small scale water power or biomass, including wood, and any combustible municipal or industrial trash or waste materials.

6. Section 490.5(dd) is amended by inserting the words "eight hours or longer" between "periods" and "of the day or night."

7. Section 490.5 is amended by adding the following subsections:

(ff) "Coolant" means the liquid which is circulated through heat exchangers for the purpose of removing heat from the air. The coolant may be circulating water, refrigerant itself, or another fluid.

(gg) "Energy that would otherwise be wasted" means any heating or cooling energy rejected by any equipment or process, which can be employed directly or indirectly to provide for space heating or cooling or for domestic water heating without increasing the load on the original equipment.

(hh) "Intermediate season" means any time when both heating and cooling are being supplied to the entire building at different times on the same day, or are being supplied at the same time to different spaces in the building.

(ii) "Reheat" means the process of raising the temperature of chilled supply air before introduction into living space.

(jj) "Work station" means the location within a room where an employee ordinarily performs his or her principal work related tasks.

§ 490.12 HVAC systems with capability for simultaneous heating and cooling.

(a) * * *

8. Section 490.12(a) is amended by adding the following new paragraph:

(3) During the intermediate season, at those times or in those areas where heat is being supplied to a room, operators of HVAC systems must comply with the requirements of paragraph (a)(1). During the intermediate season, when cooling, operators must comply with the requirements of paragraph (a)(1), or alternatively with (b)(1)(ii) for operators of fan-coil, induction, baseboard or similarly operated units, or (d)(1)(i) and (ii) for operators of "all-air" systems.

9. Section 490.12(b)(1) is revised to read as follows:

Operators of systems where the cooling or heating of room air takes place in equipment located in the occupied space (fan coil, induction, baseboard or similarly operated units) shall set space-conditioning control devices in accordance with the requirements of paragraph (a), or alternatively in the following manner:

10. Section 490.12(d) (1) is amended by deleting the phrase "by the supply air temperature or volume" and substituting for it the phrase "by varying the temperature or flow volume of air which is introduced into the occupied space".

11. Section 490.12(e) is amended by redesignating paragraphs (3), (4) and (5) as paragraphs (5), (6) and (7), repectively, and by adding two new paragraphs (3) and (4), as follows:

(3) The use of reheat is prohibited, except in those cases where a licensed professional engineer certifies that adequate temperature control cannot be achieved without the use of reheat. When reheat is used, the temperature of the air leaving the cooling coils must be 60 degrees F. or greater, unless the room temperature is 78 degrees F. or greater, in which case a lower supply air temperature is permitted.

(4) When compliance with the requirements of paragraphs (b)(1), (d)(1), or (e)(2) of this section would subject the compressor to the likelihood of damage, the coolant temperature may be lowered to the temperature level necessary to prevent such damage.

12. Section 490.13(a) is amended by adding "and repair" after "accuracy."

§ 490.13 Requirement for accuracy of space-conditioning control devices.

13. Section 490.13(b) is amended by inserting the words "or relocate"

between the words "alter" and "a" and by deleting the words "with the intent of having that device function inaccurately", and adding in its place "to thwart the intent of these regulations, or to bring about room temperatures prohibited elsewhere in these regulations".

14. Section 490.14(a) is amended by adding the following paragraph (5):

§ 490.14 Regulation of building temperatures during unoccupied periods.

(a) * * *

(5) When a building is heated by a heat pump such that the requirements of paragraph (a) (1) and (2) of this section may result in higher monthly peak demand or increased monthly energy consumption, or both, the space-conditioning control device during unoccupied periods may be set at 60 degrees F.

15. Section 490.15 is amended by adding the following sentence at the end thereof:

§ 490.15 Auxiliary heaters.

When a space heater is in use in a particular room or at a particular work station, the temperature in that room or at that work station shall not be brought above 65 degrees F.

16. Section 490.17(c) is amended by adding a new paragraph (7) as follows:

§ 490.17 Measurement techniques.

(c) * * *

(7) Any temperature measurement shall be taken at normal breathing level, or between four and six feet from the floor.

17. Section 490.17 is amended by deleting the word "or" from paragraph (c)(1)(ii), deleting the period at the end of paragraph (c)(1)(iii) and substituting in its place a semicolon and adding after the semicolon the word "or", and adding a paragraph (c)(1)(iv) as follows:

(iv) the average of thermometer readings taken at representative work stations in the room.

18. Section 490.17 is amended by adding paragraph (d) as follows:

(d) Before setting thermostats at the required level, the operator shall insure that the HVAC distribution system is properly balanced in accordance with generally accepted industry practice.

19. Section 490.18(a)(2) is amended by adding "cold well water" between "outdoor air" and "and/or evaporation effect", and by adding a comma after "outdoor air".

§ 490.18 [Amended]

20. Section 490.23(a) is amended by adding "and repair" after "accuracy."

§ 490.23 [Amended]

21. Section 490.31(a)(5) is amended by deleting the word "and" from clause (ii), deleting the period at the end of clause (iii) and substituting in its place a semicolon, and adding clauses (iv) and (v) as follows:

§ 490.31 General exemptions.

(a) * * *

(5) * * *

(iv) To protect the health of individuals required by security, safety or health codes to wear special or protective clothing to perform manufacturing inspections or other industrial functions; or

(v) With respect to restrictions on heating only, to protect the health of persons in workplace or school shower and changing rooms where showers are considered a required part of customary work or school procedure.

22. Section 490.31(a) is amended to add the following new paragraph (7):

(7) Where nutritional, recreational, and other facilities are specifically designated for use by senior citizens, the thermostat may be adjusted to raise the dry-bulb temperature to 70 degrees F. during the heating season; except that this exemption applies only when senior citizens' activity is being conducted and only to those portions of the facilities used for senior citizen activity.

23. Section 490.34 is revised to read as follows:

§ 490.34 Scope of exceptions or exemptions.

When an exemption is claimed or an exception granted, the building owner or operator, or both, shall, upon notification, and without undue delay, take action to change the temperature in the space affected by that exception or exemption to comply with temperature limits specified by the exemption or exception. Such adjustments shall be made in a manner consistent with maximum energy savings.

24. A new section, 490.36, Alternate Plan Exemption, is added as follows:

§ 490.36 Alternate plan exemption.

(a) An owner or operator of a covered building is exempted from the requirements of Subparts B and C of this part if the owner or operator—

(1) is setting space-conditioning control devices so that energy is not consumed to raise the room dry-bulb temperature above 68 degrees F. or to lower the room dry-bulb temperature below 74 degrees F.;

(2) has instituted since the effective date of these regulations or is instituting in the covered building other energy conservation measures, such as lighting reduction, insulation, weatherstripping, changed hours of operation, or installation of energy control systems, which have, in conjunction with the temperature restrictions set forth in paragraph (1) of this section, conserved as much energy as would have been conserved by compliance with the temperature restrictions set forth in Subparts B and C; and

(3) presents proof of the required energy savings upon request by a State or Federal official, which must include, but is not limited to, the most current utility or fuel, or both, consumption data available at the time of inspection and data for the corresponding period for the previous two years.

(b) An owner or operator of a covered building need not apply to DOE for an exemption under this section. An owner or operator who wants to claim this exemption may do so by complying with this section (and § 490.43) and by presenting the appropriate exemption information noting the type of exemption and the supporting information required by paragraph (a)(3) of this section to a State or Federal inspector at the time of an inspection.

(c) This exemption shall not be available in jurisdictions which have had comparable programs approved under § 490.35, unless the approved program allows such exemption and the owner or operator has taken the proper steps under the program to qualify for the exemption.

[FR Doc. 80-16042 Filed 5-23-80; 8:45 am]
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Federal Register

Tuesday
May 27, 1980

Part VIII

Department of Health and Human Services

Office of Human Development Services

Child Abuse and Neglect Prevention and Treatment Program; Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Human Development Services

45 CFR Part 1340

Child Abuse and Neglect Prevention and Treatment Program

AGENCY: Office of Human Development Services, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed regulation clarifies, simplifies, and revises the rules governing the Child Abuse and Neglect Prevention and Treatment Program and the coordination of Federal activities related to child abuse and neglect. Included are changes made necessary by the 1978 amendments to the Child Abuse Prevention and Treatment Act. None of these changes are major.

DATE: Consideration will be given to written comments received by July 11, 1980

ADDRESSE: Address comment to: Frank Ferro, Associate Chief, Children's Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, D.C. 20013.

Comments will be available for inspection in Room 3758 of the Department's Offices at 400 Sixth Street, SW., Washington, D.C., from 9:00 a.m., to 5:30 p.m., EST, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jay D. Olson, Special Assistant to the Director, National Center on Child Abuse and Neglect, Children's Bureau, P.O. Box 1182, Washington, D.C. 20013, (202) 755-0590.

SUPPLEMENTARY INFORMATION: The extension of the Child abuse Prevention and Treatment act through September 30, 1981 became law on April 24, 1978. The extension contained several changes in the Act which require minor changes in the regulations. In addition, the Children's Bureau, in the Office of Human Development Services, is taking this opportunity to clarify and simplify the existing regulation in accordance with the Department's "Operation Common Sense" initiative. This proposed regulation incorporates the statutory changes and the Department's requirements for clearer and more useful rules.

Proposed Modification of the Regulation

1. The current regulation includes four subparts organized as follows: Subpart A—General Provisions; Subpart B—Demonstrations, Technical Assistance, and Other Activities; Subpart C—Child Abuse and Neglect Grants to States under the Act and under Title IV of the Social Security Act; and Subpart D—Coordination of Federal Programs and Activities Related to Child Abuse and Neglect. The portions of the regulation included in Subparts A, B and C were developed in 1974 and correspond to the order of Sections in the Child Abuse Prevention and Treatment Act of 1974 ("the Act"). Subpart D was added in 1976 after extensive interagency discussions resulting in the policies contained in that Subpart. (Also, Subpart C at 1340.3-2(a)(2) explains that child abuse and neglect programs, assisted under Parts A and B of Title IV of the Social Security Act, must meet the requirements of Pub. L. 93-247, as amended, and the Social Security Act in accordance with regulations published in 45 CFR Part 220.)

This proposed regulation is also organized in four Subparts (A, B, C and D). Subpart A, as in the current regulation, contains a statement of purpose and scope, a definition section and cross references to applicable Department-wide regulations. Specific requirements for grants to States under section 4(b)(1) and (2) of the Act (42 U.S.C. 5103(b)(1) and (2)) previously included in Subpart C, are now included as proposed Subpart B, Grants to States.

Requirements for the funding of grants and contracts under other provisions of the Act are currently included in Subpart B. That subpart has been redesignated Subpart C, Discretionary Grants and Contracts. Proposed Subpart D contains, as it does in the current regulation, requirements for the coordination of Federal child abuse and neglect activities.

Significant Modifications Contained in the Proposed Regulation

In addition to the reorganization of the existing regulation, other substantive changes are proposed, the most important of which are described below.

1. Subpart A, General Provisions, has been shortened considerably by the elimination of those sections which repeat provisions found in 45 CFR Part 74, Administration of Grants. The Department is in the process of removing provisions from program regulations which duplicate Part 74 and inserting instead cross references to Part 74. This subpart also contains a list of other Department regulations that apply to grants and contracts awarded under the Act.

The current regulation, at § 1340.1-11, states that programs and projects may be approved for not more than five years. This limitation has been deleted. The duration of programs and projects will be stated in program announcements, which will be published in the Federal Register.

Subpart A (in § 1340.1-6) also includes a provision related to a possible conflict of interest by employees or individuals participating in a program or project under the Act. That prohibition has been deleted from the regulation but continues in effect and is stated in each award made under the Act.

Definitions originally in the current Subpart A and Subpart D (Coordination of Federal Activities) have been consolidated here. Certain definitions have been shortened or eliminated. The definition of child abuse and neglect has been clarified to include specific sub-definitions of "sexual abuse" and "sexual exploitation" which conform to amendments to the Act. The addition of "sexual exploitation" in the section on definitions (§ 1340.2) expands the definitional requirement for States applying for a State grant under Section 4(b)(1) of the Act. All applicant States must have a definition of child abuse and neglect that is in accordance with all aspects of the definition in § 1340.2, including "sexual exploitation." It will be necessary for some States to revise their State law in order to comply with this new definitional requirement. Therefore, the effective date for a State to comply with the requirement that "sexual exploitation" be included in its definition of child abuse and neglect will be no later than the close of the general legislative session that convenes next after the effective date of this recodified regulation.

A number of States include in the statutory definition of child abuse and neglect "failure to provide medical or health care." States are not required to include this provision in their definition of abuse and neglect in order to satisfy the definitional requirement for eligibility under § 1340.14(a). Congress indicated in the legislative history that "no parent or guardian who in good faith is providing to a child treatment solely by spiritual means—such as prayer—according to the tenants and practices of a recognized church through a duly accredited practitioner shall 'for that reason alone' be considered to have neglected the child." We have therefore noted the legislative history in the proposed regulation, under the definition of "negligent treatment or maltreatment."

The definition of a "child" has also been modified to reflect the amendment to the Act providing that a child is "a person under the age of eighteen or the age specified by the child protection law

of the State." In accordance with the amendments to the Act the definition of Advisory Board on Child Abuse and Neglect has been expanded to include at least three public members appointed by the Secretary.

2. Subpart B, Grants to States, governs grants awarded to States under sections 4(b)(1) and (2) of the Act, 42 U.S.C. 5103(b)(1) and (2). This Subpart has been reorganized for the sake of clarity and to simplify the State eligibility process. The formula for allocating funds to States has been revised to change the current base amount from $20,000 to $25,000 per State. The total State allotment consists of the base amount plus an amount bearing the same ratio to the total amount remaining available as the number of the children under the age of eighteen in the State bears to the number of childen in all States. The base amount can be varied by the Commissioner to meet changed needs. The additional amount for each State is based on the total number of children, a clearly verifiable figure equal to the total potential population at risk of child abuse and neglect. This formula, with the exception of the increase in the base amount from $20,000 to $25,000, is the same as is contained in the current regulation.

With regard to eligibility requirements the State must meet, the proposed rule continues the policy of the current regulation that States must have in effect a State statute on confidentiality of records which makes improper release of the information a crime. Protection of the information and the related privacy rights of the child and his/her parents or guardians is critical to helping families solve their problems free from the harm caused by unnecessary disclosure. The policies governing the confidentiality of the records are more likely to receive public scrutiny and therefore to provide better protection if States must enact them into law. By placing them in a statute, the policies will also be less susceptible to continued change.

We have also maintained in this proposal the current requirement that States, by statute, require that certain persons must report and insure by statute or administrative procedure that all others may report known and suspected instances of child abuse and neglect. Here again, we have reaffirmed our decision that a statute rather than a mere administrative policy is needed to insure the reporting by certain persons. The proposed rule requires that "specified persons" be required to report. A State may choose to specify all persons in the State or only certain categories of persons, e.g., health, social services, law enforcement, and education professionals.

The proposed rule continues the requirement that reports be received and investigated by a different properly constituted authority when the report of known or suspected child abuse or neglect involves the acts or omissions of the agency to which the report would ordinarily be made. Without this requirement, the alleged offending State agency would be totally in control of investigations of alleged abuse or neglect by its employees. This would not provide outside accountability and protection for children in State institutions or other settings and would increase the potential that agency malfeasance would be undetected.

The proposed rule also continues the current State eligiblity requirement that States must provide immunity to persons reporting known or suspected child abuse and neglect, but only for reports made in good faith. The proposed rule adds the good faith requirement to the regulation.

This means that States need not provide immunity for persons reporting purported child abuse or neglect merely to harass, embarass, or otherwise unjustifiably harm another individual. A number of States already meet this requirement through a general statute of immunity for persons reporting a crime or other offense.

The proposed rule continues the requirement that the State must provide for the appointment of a guardian ad litem in every case involving an abused or neglected child which results in a judicial proceeding. However, it is our belief that in criminal proceedings, the State or county attorney represents the child as well as the other members of the public and that therefore a guardian ad litem is not required in such proceedings. We request specific comments on this point. We have restated the requirement that a person who is not titled "guardian ad litem" meets the requirement so long as that person is assigned and conducts the functions of representing and protecting the rights and best interests of the child.

3. Subpart C, Discretionary Grants and Contracts, condenses and simplifies the regulations by referring to the statutory provisions with regard to the purposes of such awards. Awards under this subpart will continue to be awarded according to the criteria established by the Secretary to provide for equitable distribution among geographic areas and urban and rural areas. This subpart also describes the procedures for announcing and making these awards. The proposed rule for protecting the confidentiality of records related to child abuse and neglect projects supported under this subpart has been made fully consistent with the confidentiality requirement of eligiblity.

4. Subpart D, Coordination of Federal Activities, explains the functions of the Advisory Board on Child abuse and Neglect and the National Center on Child Abuse and Neglect in the Federal coordination process. It also lists reports and materials to be submitted to the Advisory Board to improve coordination. The proposed rule has been revised to include planned activities as well as current program implementation to reflect the change in the Act. It is not, however, the purpose of this subpart to alter the basic responsibility of individual Federal agencies to administer and manage their own programs and activities.

This proposed regulation is issued under the authority of the Child Abuse Prevention and Treatment Act (Pub. L. 93-247), as amended. (42 U.S.C. 5101 et seq.)

The proposed regulation will not alter the costs resulting from the Act significantly. In fact, clarifying requirements for applicants for State grants and other grants or contracts should slightly reduce the administrative burden and the costs for the applicants.

The regulation has been reviewed under Executive Order 12044 criteria. It does not require a regulatory analysis, since it does not meet the threshold of the criteria on economic impact.

(Catalog of Federal Domestic Assistance Progam Number 13.628, Child Abuse and Neglect Prevention and Treatment)

Dated: January 18, 1980.

Manuel Carballo,

Acting Assistant Secretary for Human Development Services.

Approved: May 20, 1980.

Patricia Roberts Harris,

Secretary.

Part 1340 of 45 CFR is amended as follows:

PART 1340—CHILD ABUSE AND NEGLECT PREVENTION AND TREATMENT

Subpart A—General Provisions

Sec.

Subpart B—Grants to States

Authority: 42 U.S.C. 5101 et seq.

Subpart A—General Provisions

§ 1340.1 Purpose and scope.

(a) This part implements the Child Abuse Prevention and Treatment Act of 1974, as amended (Pub. L. 93–247, 42 U.S.C. 5101, et seq.). Through the activities of the Children's Bureau's National Center on Child Abuse and Neglect and other Federal agencies, this program seeks to assist agencies and organizations at the national, State and community levels in their efforts to improve and expand child abuse and neglect prevention and treatment activities.

(b) The program seeks to meet these goals through:

(1) Conducting activities directly (by the Center);

(2) Making grants to States to improve and expand their child abuse and neglect prevention and treatment programs;

(3) Making grants to and entering into contracts with public or private agencies and organizations for: Research, demonstration and service improvement programs and projects, and training, technical assistance and informational activities; and

(4) Coordinating Federal activities related to child abuse and neglect.

This part establishes the standards and procedures for conducting the grant, contract and coordination activities.

(c) Section 4(b)(3) of the Act applies certain requirements to the activities related to child abuse and neglect assisted under part A or B of Title IV ("titles IV–A and IV–B") of the Social Security Act. This provision is currently implemented by regulation at 45 CFR Part 231.

(d) Federal financial assistance is not available under the Act for the construction of facilities.

§ 1340.2 Definitions

For the purposes of this part:

"A properly constituted authority" is an agency with the legal power and responsibility to perform an investigation and take necessary steps to prevent and treat child abuse and neglect. A properly constituted authority may include a legally mandated, public or private child protective agency, or the police, the juvenile court or any agency thereof.

"Act" means the Child Abuse Prevention and Treatment Act, 42 U.S.C. 5101, et seq.

"Advisory Board" means the Advisory Board on Child Abuse and Neglect, established by the Secretary under the Act, and composed of representatives of Federal agencies with responsibility for programs and activities related to child abuse and neglect and at least three public members appointed by the Secretary.

"Center" means the National Center on Child Abuse and Neglect established by the Secretary under the Act to administer this program.

"Child" means a person under the age of eighteen or the age specified by the child protection law of the State.

"Child abuse and neglect" means the physical or mental injury, sexual abuse, sexual exploitation, negligent treatment, or maltreatment of a child by a person responsible for the child's welfare under circumstances indicating harm or threatened harm to the child's health or welfare. The term encompasses both acts and omissions on the part of a responsible person.

(1) "Sexual abuse" includes rape, incest, and sexual molestation, as those acts are defined by State law, by a person responsible for the child's welfare.

(2) "Sexual exploitation" includes allowing, permitting, or encouraging a child to engage in prostitution, as defined by State law, by a person responsible for the child's welfare; and allowing, permitting, encouraging or engaging in the obscene or pornographic photographing, filming, or depicting of a child for commercial purposes as those acts are defined by State law, by a person responsible for the child's welfare.

(3) "Negligent treatment or maltratment" includes failure to provide adequate food, clothing or shelter.

Note.—The legislative history of the Act states, that a parent or guardian legitimately practicing his religious beliefs who threby does not provide specific medical treatment for a child is for that reason alone not considered to be a negligent parent. No parent or guardian who in good faith is providing treatment to a child solely by spiritual means, such as prayer, according to the tenets and practices of a recognized church through a duly accredited practitioner shall for that reason alone be considered to have neglected the child.

(4) "Threatened harm to a child's health or welfare" means a substantial risk of harm to the child's health or welfare.

(5) "A person responsible for a child's welfare" includes the child's parent, guardian, foster parent, an employee of a public or private residential home or facility or other person legally responsible under State law for the child's welfare in a residential setting.

"Commissioner" means the Commissioner for Children, Youth and Families of the Department of Health and Human Services.

"Grants" includes grants and cooperative agreements.

"Secretary" means the Secretary of Health and Human Services, or other HHS official or employee to whom the Secretary has delegated the authority specified in this part.

"State" means each of the several States, the District of Columbia, Puerto Rico, American Samoa, the Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territories of the Pacific.

§ 1340.3 Applicability of Department-wide regulatons.

(a) The following HHS regulations are applicable to all grants made under this part:

45 CFR Part 16—Department grant appeals process
45 CFR Part 46—Protection of human subjects
45 CFR Part 74—Administration of grants
45 CFR Part 75—Informal grant appeals procedures
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80
45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance.

(b) The following regulations are applicable to all contracts awarded under this part:

41 CFR Chapter 1—Federal procurement regulations.
41 CFR Chapter 3—Federal procurement regulations—Department of Health and Human Services.

Subpart B—Grants to States

§ 1340.10 Purpose of this subpart.

This subpart sets forth the requirements and procedures States must meet in order to receive discretionary grants to improve or expand State child abuse and neglect prevention and treatment programs under sections 4(b) (1) and (2) of the Act (42 U.S.C. 5103(b) (1) and (2)).

§ 1340.11 Allocation of funds available.

(a) The Commissioner shall allocate the funds available for grants to States for each fiscal year among the States on the basis of the following formula:

(1) An amount of $25,000 or such other amount as the Commissioner may determine; plus

(2) An additional amount bearing the same ratio to the total amount made available for this purpose (reduced by the minimum amounts allocated to the States under paragraph (a)(1) of this section) as the number of children under the age of eighteen in each State bears to the total number of children under eighteen in all the States. Annual estimates of the number of children under the age of eighteen, provided by the Bureau of the Census of the Department of Commerce, are used in making this determination.

(b) If a State has not qualified for assistance under the Act and this subpart prior to a date designated by the Commissioner in each fiscal year, the amount previously allocated to the State shall be allocated among the eligible States or used by the Center for such other purposes under the Act as the Commissioner shall determine.

§ 1340.12 Application process.

(a) The Governor of the State shall designate the State office, agency, or organization which may apply for assistance under this subpart. The State office, agency, or organization need not be limited in its mandate or activities to child abuse and neglect.

(b) Grant applications will be solicited each Federal fiscal year by the publication in the Federal Register of a notice of the availability of funds for State grants and program priorities.

(c) Grant applications must include a description of the activities presently conducted by the State and its political subdivisions in preventing and treating child abuse and neglect, the activities to be assisted under the grant, a statement of how the proposed activities are expected to improve or expand child abuse prevention and treatment programs in the State, and other information required by the Commissioner.

(d) States shall provide with the grant application a statement signed by the Governor that the State meets the requirements of the Act and of this subpart. This statement shall be in the form and incude the documentation required by the Commissioner.

§ 1340.13 Approval of applications.

(a) The Commissioner shall approve an application for an award for funds under this subpart if he or she finds that:

(1) The State is qualified under the Act and this subpart and has met all requirements of eligibility under § 1340.14 except for the definitional requirement of § 1340.14(a) with regard to the definition of "sexual exploitation" (see § 1340.2(2))." The State must include "sexual exploitation" in its definition of child abuse and neglect no later than the close of the general legislative session that convenes next after the effective date of this recodified regulation.

(2) The funds are to be used to improve and expand child abuse or neglect prevention or treatment programs, in accordance with the funding available and program priorities established in the Federal Register notice; and,

(3) The State is otherwise in compliance with these regulations.

(b) At the time of an award under this subpart, the amount of funds not obligated from an award made eighteen or more months previously shall be subtracted from the amount of funds under the award, unless the Secretary determines that extraordinary reasons justify the failure to so obligate.

§ 1340.14 Eligibility requirements.

In order for a State to qualify for an award under this subpart, the State must satisfy each of the following requirements:

(a) *Definition of Child Abuse and Neglect.* Wherever the rquirements below use the term "Child Abuse and Neglect" the State must define that term in accordance with § 1340.2.

(b) *Reporting.* The State must provide by statute that specified persons must report and by statute or administrative procedure that all other persons are permitted to report known and suspected instances of child abuse and neglect to a child protective agency or other properly constituted authority.

(c) *Immunity.* The State must have in effect a statute which provides all persons reporting known or suspected child abuse and neglect, in good faith with immunity from civil or criminal prosecution arising out of such reporting.

(d) *Investigations.* The State must provide for the prompt initiation of an appropriate investigation by a child protective agency or other properly constituted authority to substantiate the accuracy of all reports of known or suspected child abuse or neglect. This investigation may include the use of reporting hotlines, contact with central registers, field investigations and interviews, home visits, consultation with other agencies, medical examinations, psychological and social evaluations, and reviews by multidisciplinary teams.

(e) *Institutional child abuse and neglect.* The State must have a statute or administrative procedure requiring that when a report of known or suspected child abuse or neglect involves the acts or omissions of the agency, institution, or facility to which the report would ordinarily be made, a different properly constituted authority must receive and investigate the report and take appropriate protective and corrective action.

(f) *Emergency services.* If an investigation of a report reveals that the reported child or any other child under the same care is in need of immediate protection, the State must provide emergency services to protect the child's health and welfare. These services may include emergency caretaker or homemaker services; emergency shelter care or medical services; review by a multidisciplinary team; and, if appropriate, criminal or civil court action to protect the child, to help the parents or guardians in their responsibilities and, if necessary, to remove the child from a dangerous situation.

(g) *Guardian ad litem:* In every case involving an abused or neglected child which results in a judicial proceeding, the State must insure the appointment of a guardian ad litem or other individual whom the State recognizes as fulfilling the same functions as a guardian ad litem, to represent and protect the rights and best interests of the child. This person may, but need not, be the attorney presenting the evidence aleging the child abuse or neglect so long as his legal responsibility includes representing the rights, interests, welfare, and well-being of the child. This requirement may be satisfied: (1) By a statute mandating the appointments; (2) by a statute permitting the appointments, accompanied by a statement from the Governor that the appointments are made in every case; or (3) in the absence of a specific statute, by a formal opinion of the Attorney General that the appointments are permitted, accompanied by a Governor's statement that the appointments are made in every case.

(h) *Prevention and treatment services:* The State must demonstrate that there are, throughout the State, procedures and services adequate to deal effectively with child abuse and neglect cases. These procedures and services shall include: (1) Administrative, training, and management procedures; (2) institutional and other facilities (public and private); (3) trained personnel; (4) multidisciplinary

programs and services for the receipt, investigation and verification of reports; (5) the determination of social service and medical needs; (6) the provision of needed social and medical services; and (7) when necessary, resort to criminal or juvenile court.

(i) *Interagency and multidiscipinary cooperations.* The State must provide for the cooperation of law enforcement officials, courts of competent jurisdiction, and all appropriate State agencies providing services related to the prevention, identification and treatment of child abuse and neglect. This cooperation may include joint consultation and services, joint planning, joint case management, joint public education and information services, utilization of each other's facilities, and joint staff and other training at the State and local levels.

(j) *Parental organizations.* The State must insure that to the extent feasible parental organizations combatting child abuse and neglect receive preferential treatment in the planning and implementation of programs. These parental organizations include: Organizations established specifically for these purposes (such as parental self-help or treatment groups); and parental organizations with more general purposes which adopt as one specific objective the prevention and treatment of child abuse and neglect.

(k) *Public education.* The State must disseminate information to the general public about the problem of child abuse and neglect and available prevention and treatment programs and facilities.

(l) *Maintenance of effort.* The State must provide that the aggregate amount of State funds used for programs or projects related to child abuse and neglect assisted by State funds shall not be reduced below the level provided for Federal fiscal year 1973. The State must also set forth policies and procedures designed to assure that Federal funds made available under the Act for any fiscal year will be used to supplement and to the extent practicable increase the level of State funds which would be available for such programs and projects in the absence of Federal funds.

(m) *Confidentiality.* (1) The State must provide by statute that all records concerning reports and reports of child abuse and neglect are confidential and that their unauthorized disclosure is a criminal offense.

(2) If a State chooses to, it may authorize by statute disclosure to any or all of the following persons and agencies, under limitations and procedures the State determines:

(a) The agency (agencies) or organizations (including its designated multidisciplinary case consultation team) legally mandated by any Federal or State law to receive and investigate reports of known and suspected child abuse and neglect;

(b) A court, under terms identified in State statute;

(c) A grand jury;

(d) A properly constituted authority (including its designated multidisciplinary case consultation team) investigating a report of known or suspected child abuse or neglect or providing services to a child or family which is the subject of a report;

(e) A physician who has before him or her a child whom the physician reasonably suspects may be abused or neglected;

(f) A person legally authorized to place a child in protective custody when the person has before him or her a child whom he or she reasonably suspects may be abused or neglected and the person requires the information in the report or record in order to determine whether to place the child in protective custody;

(g) An agency authorized by a properly constituted authority to diagnose, care for, treat, or supervise a child who is the subject of a report or record of child abuse or neglect;

(h) A person who is responsible for the child's welfare, with protection for the identity of any person reporting known or suspected child abuse or neglect and any other person where the person or agency making the information available finds that disclosure of the information would be likely to endanger the life or safety of such person;

(i) A child named in the report or record alleged to have been abused or neglected or (as his/her representative) his/her guardian or guardian ad litem;

(j) An appropriate State or local official responsible for administration of the child protective service or for oversight of the enabling or appropriating legislation, carrying out his or her official functions; and

(k) A person, agency, or organization engaged in a bonafide research or evaluation project, but without information identifying individuals named in a report or record, unless having that information open for review is essential to the research or evaluation, the appropriate State official gives prior written approval, and the child, through his/her representative as cited in paragraph (i), gives permission to release the information.

(3) Nothing in this section shall be interpreted to prevent the properly constituted authority from summarizing the outcome of an investigation to the person or official who reported the known or suspected instances of child abuse or neglect or to affect a State's laws or procedures concerning the confidentiality of its criminal court or its criminal justice system.

(4) HHS and the Comptroller General of the United States or any of their representatives shall have access to records, as required under 45 CFR 74.24.

Subpart C—Discretionary Grants and Contracts

§ 1340.20 General.

(a) Under the Act, the Commissioner shall carry out the functions and activities listed in section 2(b) of the Act, directly, by grant, or by contract.

(b) The Commissioner is authorized to make grants or contracts to public agencies or nonprofit private organizations for demonstration or service programs and projects designed to prevent, identify, and treat child abuse and neglect. Grants or contracts under this subsection may be for any of the purposes stated in section 4(a)(1) of the Act.

§ 1340.21 Procedures for making awards under this subpart.

(a) The Commissioner will publish in the Federal Register program announcements specifying the application procedures, the project goals and the program purposes for which grants under this subpart are available, and the criteria which will be applied in awarding the grants.

(b) Contracts will be awarded in accordance with the requests for proposals announced in the *Commerce Business Daily.*

(c) Research priorities will be proposed and published in the Federal Register for a public comment period of sixty days or more before they are established as final priorities.

§ 1340.22 Confidentiality.

All projects and programs supported under the Act must hold all information related to personal facts or circumstances about individuals involved in those projects or programs confidential and shall not disclose any of the information in other than summary, statistical, or other form which does not identify specific individuals, except in accordance with § 1340.14(m).

Subpart D—Coordination of Federal Activities

§ 1340.30 Purpose of this subpart.

The purpose of this subpart is to establish procedures for coordinating the activities among Federal agencies

responsible for programs related to child abuse and neglect. These procedures are designed to:

(a) Clarify the respective roles of these Federal agencies in the prevention and treatment of child abuse and neglect;

(b) Compile and centrally maintain information about the activities of the agencies;

(c) Share the results and data generated by programs and activities;

(d) Establish and maintain appropriate program interaction; and

(e) Prevent unnecessary duplication.

§ 1340.31 Coordination process.

(a) The Advisory Board is responsible for assisting the Secretary in coordinating Federal programs and activities related to child abuse and neglect.

(b) The Advisory Board performs its responsibilities by:

(1) Meeting periodically to share information on how best to maximize the effectiveness of Federal efforts;

(2) Arranging to have the regional office representatives of Federal agencies undertake joint planning and coordination of child abuse and neglect activities through means such as inter-agency committees and agreements;

(c) Whenever it finds that any planned activities appear to represent an inappropriate duplication or overlapping of efforts with those of another agency or that more effective coordination can be achieved, the Advisory Board through the Assistant Secretary for Human Development Services will bring the matter and its recommendations to the attention of the agencies involved. In these cases, the Advisory Board will request a report on how the agencies involved propose to coordinate their activities and a timetable for the action proposed. In the event that there is an urgent need, the Advisory Board will set a deadline for the resolution of the problem.

(d) The Advisory Board will report to the Secretary on a regular basis if there are inappropriate duplications or overlap of efforts in planned activities.

§ 1340.32 Reports and materials.

In support of the Advisory Board, the Center will request all member Federal agencies to provide information regarding their child abuse and neglect activities at a time sufficiently prior to final agency action to allow for review and coordination by the Advisory Board. This information shall include:

(a) An annual written report on (1) long range plans and budget projections, (2) contemplated activities and budget projections for the succeeding fiscal year with a specific description of what those activities are to achieve and how they relate to existing activities; and (3) the results and accomplishments of activities conducted during the previous fiscal year and a recapitulation of funds expended;

(b) Information on additional activities planned after the submission of the annual written report;

(c) Copies of statements of work for proposed contracts or program announcements for proposed grants;

(d) Brief statements of the subject matter, methodology, and objectives of solicited or unsolicited activities tentatively approved for funding, prior to the time of award;

(e) Notices of grant and contract awards, at the time of award; and

(f) Draft and final regulations or other requirements, guidelines, and standards.

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR NOTICE FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
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DOT/NHTSA	MSPB/OPM		DOT/NHTSA	MSPB/OPM
DOT/RSPA	LABOR		DOT/RSPA	LABOR
DOT/SLSDC	HEW/FDA		DOT/SLSDC	HEW/FDA
DOT/UMTA			DOT/UMTA	
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Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

List of Public Laws

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This is a continuing listing of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the Federal Register but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202-275-3030).

H.R. 5673 / Pub. L. 96-245 To authorize the use of certified mail for the transmission or service of matter which, if mailed, is required by certain Federal laws to be transmitted or served by registered mail, and for other purposes. (May 21, 1980; 94 Stat. 347) Price $1.00.

Rules Going Into Effect Today